
California Health Information Exchange Operational Plan

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1. Introduction

The American Recovery and Reinvestment Act (ARRA), specifically the provisions of the Health Information Technology for Economic and Clinical Health Act (HITECH), provides a tremendous opportunity to accelerate HIT adoption rapidly and advance Health Information Exchange (HIE) throughout the State with a particular focus on Medicare and Medicaid providers. The Act commits up to \$27.3 billion¹ in grants, loans, and incentives to Medicare and Medicaid providers to support meaningful use of EHRs in a secure, patient-centric environment.

In response to HITECH, CMS issued a Notice of Proposed Rule Making (NPRM) on the EHR Incentive Program providing a framework for defining “meaningful use of certified EHR technology” and the rules by which eligible professionals and eligible hospitals will demonstrate meaningful use for the Medicare and Medicaid programs. The proposed approach to meaningful use is an incremental, phased implementation across three stages, reflecting the expectation that the health IT infrastructure will change over time. The California Operational Plan focuses on meaningful use criteria for which HIE is “essential”, and those for which it is an “enabler”, described in Table 1, recommending strategies to optimize access to incentives while moving toward HIE.

California is well-positioned to respond to ARRA and HITECH requirements. California is committed to advance Health IT and HIE. This commitment was demonstrated in Executive Order S-12-06,² issued in July 2006, which resulted in the California Health Information Technology Study.³ In March 2007, Governor Schwarzenegger issued Executive Order S-06-07⁴ calling for the advancement of Statewide HIT adoption to increase quality, strengthen transparency and promote accountability in the health care sector. Soon after ARRA was enacted, the Governor appointed a Deputy Secretary, Health Information Technology (the “Deputy Secretary”) within the Health and Human Services agency (CHHS). The Secretary of Health and Human Services convened an eHealth Advisory Board to provide guidance in the development of the Strategic Plan and this Operational Plan.

¹ Centers for Medicare and Medicaid Services (CMS) regulatory impact analysis on Notice of Proposed Rulemaking for the EHR Incentive Program. The estimated range is substantially less than the \$44.7 billion CMS previously assumed in its ARRA implementation plan.

² Executive Order S-12-06 by the Governor of the State of California, July 24, 2006.<http://gov.ca.gov/executive-order/2616>.

³ California Health Information Technology Study: Input to the California Health Data Exchange Roadmap, Accenture, January 2007. See <http://www.hmoHELP.ca.gov/library/reports/news/CA%20HIT%20Study%202007.pdf>

⁴ Executive Order S-06-07 by the Governor of the State of California, March 14, 2007. <http://gov.ca.gov/index.php?/executive-order/5626/>.

1.1 Strategic Plan

Over the course of four months, from April to August 2009, the State guided an open, inclusive, and transparent planning effort to develop its HIE Strategic Plan.⁵ The HIE Strategic Plan acts as the foundation to the state's HIE operational planning and implementation effort. Importantly, the Strategic Plan sets forth a vision for statewide HIE, and outlines goals and priority objectives. In addition, the plan includes an environmental scan of health IT adoption and level of HIE use in California, provides an analysis of technical, business, and finance strategies to achieve statewide HIE, outlines requirements for a not-for-profit organization that can function as a statewide governance entity (GE), and provides an approach to coordinate with Medi-Cal and state public health programs to support providers in HIE as required for meaningful use incentives.

1.2 ONC Application

After submission of the Strategic Plan, California submitted an Application to ONC to participate in the State Health Information Exchange Cooperative Agreement program, recently receiving confirmation of an award for \$38.8 million to CHHS to promote and support HIE. CHHS serves as the lead agency on HIE and HIT issues for the State. CHHS works with the Office of the State Chief Information Officer (OCIO), the Business, Transportation and Housing Agency the Department of Managed Health Care (administrators of the Medi-Cal program) and the California Department of Public Health to oversee the State's HIE and HIT related efforts. Additional funding has been received by one of the State's applicants to be a Regional Extension Center (REC): \$31 million was granted to the California Health Information Partnership and Services Organization (CalHIPSOS) to support providers in northern and southern California, excluding Los Angeles and Orange Counties, which will be used to help primary care providers adopt electronic health records. Separate funding was also received for HIT workforce development: \$31.4 million to California community colleges and not-for-profit organizations, for a total of over \$100 million awarded to the State for HIT adoption and implementation.

1.3 Operational Plan

The Operational Plan details how the California HIE Strategic Plan will be executed to enable statewide HIE. The plan outlines specific actions and roles of various stakeholders in the development and implementation of HIE services. The plan includes an annual budget over the four year grant program, in addition to high-level timelines and major milestones. Importantly, the plan outlines an approach for continuous improvement and evaluation. This plan is consistent with the State HIE Cooperative

⁵ Strategic Plan: <http://www.ehealth.ca.gov/eHealthPlan/tabid/72/Default.aspx>

Agreement Program Funding Opportunity Announcement⁶ and addresses all five ONC required HIE domains including:

- Governance
- Finance
- Technical infrastructure
- Business and technical operations
- Legal/Policy

1.4 Vision Statement

Our vision is that health care in California is built on a solid foundation of health information exchange that provides safe and secure patient and provider access to personal and population health information improving the health and well-being, safety, efficiency, and quality of care for all Californians.

1.5 Goals

The following goals were established to achieve effective HIE in California:

1. To ensure that patients have safe, secure access to their personal health information and the ability to share that information with others involved in their care.
2. To engage in an open, inclusive, collaborative, public-private process that supports widespread EHR adoption and robust, sustainable exchange of health information throughout the State.
3. To improve health care outcomes and reduce costs.
4. To maximize California stakeholders' access to critical ARRA funds.
5. To integrate and synchronize the planning and implementation of HIE, HIT, telehealth and provider incentive program components of ARRA.
6. To ensure accountability in the expenditure of public funds.

⁶ Funding Opportunity Announcement:
<http://healthit.hhs.gov/portal/server.pt?open=512&objID=1336&mode=2&cached=true>.

7. To improve public and population health through stronger public health program integration, bio-surveillance and emergency response capabilities.

1.6 Priority Objectives

California must align its HIE implementation and priorities with federal requirements to ensure that its eligible providers are able to demonstrate meaningful use and are positioned to receive the maximum incentive reimbursement and avoid future reimbursement penalties.

This Operational Plan for California is built in the context of the federal vision for EHR implementation and with the goal of supporting providers' achievement of meaningful use in the phased approach as detailed by CMS:

Stage 1 is based on "current available technological capabilities and providers' practical experiences."

Stage 1 requirements are effective for 2011 and focus on:

- Electronically capturing health information in a coded format;
- Using information to track key clinical conditions;
- Communicating captured information for care coordination purposes; and
- Reporting of clinical quality measures and public health information.

Stage 2 criteria for 2013 will likely expand upon Stage 1 criteria in the areas of disease management, clinical decision support, medication management, support for patient access to their health information, transitions in care, quality measurement, research, and bi-directional communication with public health agencies. For Stage 2, CMS may also consider applying the criteria more broadly to both inpatient and outpatient hospital settings.

Stage 3 criteria for 2015 will likely focus on achieving improvements in quality, safety and efficiency focusing on specific national high-priority conditions and decision support, patient access to self management tools, access to comprehensive patient data, and improving population health outcomes.

1.7 Scope of Operational Plan

The near-term requirements of the HIE infrastructure in California should focus on those HIE capabilities needed to support the meaningful use criteria and related HER certification criteria. Only a subset of these criteria are related to HIE, which may be divided into two groups: Those criteria for which HIE is

an *essential* element of the criterion and those criteria for which HIE is not the essence of the criterion but may be an important enabling capability. Table 1 and Table 2 below list the meaningful use criteria in each of these categories, and the HIE capabilities related to each one. These HIE capabilities, therefore, comprise functional requirements integral to the HIE infrastructure in California.

The federal government has not yet specified the criteria required for meaningful use beyond 2011. However, given the effort and lead time required to build out the HIE infrastructure in California, it is also important to consider the HIE that will be needed to support future meaningful use criteria. The meaningful use NPRM provides some general guidance in this area:

“For other objectives that are reliant on the electronic exchange of information, we are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is not yet currently available. We anticipate raising the threshold for these objectives in future definitions of meaningful use as the capabilities of HIT infrastructure increases. *The intent and policy goal with raising this threshold is to ensure that meaningful use encourages patient-centric, interoperable health information exchange across provider organizations regardless of provider’s business affiliation or EHR platform.*”⁷

The emphasized sentence characterizes the general long-term goals of the HIE infrastructure in California, and should be a consideration in near-term planning and implementation decisions.

Table 1. Meaningful Use Criteria for which HIE is Essential

Meaningful Use Criterion	Relevant HIE Capability
1. Generate and transmit permissible prescriptions electronically	Infrastructure for an EHR or EHR module to correctly address and securely* transmit an electronic prescription to the desired dispensing pharmacy in the specified standard format. The transmission may occur directly or via a third party.
2. Incorporate clinical lab-test results into EHR as structured data	Infrastructure for labs to securely* transmit structured lab results to the EHR or EHR module of the appropriate provider(s) in the specified standard format. The transmissions may occur directly between labs and EHRs or via a third party.

⁷ Notice of Proposed Rulemaking Medicare and Medicaid Programs: Electronic Health Record Incentive Program (Document ID CMS-2009-0117-0002)

Meaningful Use Criterion	Relevant HIE Capability
3. Check insurance eligibility electronically from public and private payers	Infrastructure to securely* query a payer, either manually via a web browser or automatically via Electronic Data Interchange (EDI), in the specified standard format and to receive an electronic response, either via a web browser or automatically via EDI, in the specified standard format. These transactions may occur directly between providers and payers or via a third party.
4. Submit claims electronically to public and private payers	Infrastructure to securely* transmit claims from a provider organization to a payer in the specified standard format. These transactions may occur directly between providers and payers or via a third party.
5. Provide patients with an electronic copy of their health information/discharge instructions upon request	HIE capability is required if the electronic copy is transmitted to the patient via a network, either directly (e.g. via secure email) or through a 3rd-party patient-authorized entity (e.g., a Personal Health Record). In these cases, the capability is required to correctly address and securely* transmit the information in an accepted format to the patient or the patient-authorized entity.
6. Capability to exchange key clinical information among providers of care and patient-authorized entities electronically	Infrastructure to correctly address and securely* transmit the specified types of information (problem list, medication list, etc.) in an acceptable data format from one provider to another, from a provider to a patient-authorized entity, or from a patient-authorized entity to a provider.
7. Provide patients with electronic access to their health information within 96 hours	HIE capability may simplify electronic access provided to patients via a 3rd-party patient-authorized entity, such as an “untethered” PHR. In this case, the same capability is required as for #6.

Meaningful Use Criterion	Relevant HIE Capability
8. Provide summary-of-care record for each transition of care and referral	HIE capability will simplify and promote the transition of care or referral made to a different organization, and most easily facilitate transfer of the summary-of-care record.
9. Capability to submit electronic data to immunization registries and actual submission where required and accepted	Infrastructure to securely* transmit immunization events from any hospital or outpatient facility to the appropriate immunization registry for the appropriate patient in a specified data format, and to allow immunization registries to securely* exchange data
10. Capability to provide electronic submission of reportable lab results to public health agencies and actual submission where it can be received	Infrastructure to securely* transmit lab results from any hospital laboratory to the appropriate public health agency in a specified standard format, including de-identification of the data, if required.
11. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Infrastructure to securely* transmit relevant clinical data from any hospital or outpatient facility to the appropriate public health agency in a specified standard format, including de-identification of the data, if required.

** See section 5.1.1. for discussion of security requirements for meaningful use.*

Table 2. Meaningful Use Criteria Enabled by HIE

Meaningful Use Criterion	Relevant HIE Capability
12. Generate lists of patients by specific condition to use for quality improvement, reduction of disparities, and outreach	The required capability will enable secure* transmission of clinical data from the source organization to the aggregating organization and to resolve patient-identity discrepancies in the data at the time they are requested or received.

Meaningful Use Criterion	Relevant HIE Capability
13. Report ambulatory quality measures to CMS or States	Accurate generation of ambulatory quality measures may require the electronic aggregation of clinical data from multiple organizations (as above). In this case, the same HIE capability is required as for #12 above.
14. Perform medication reconciliation at relevant encounters and each transition of care	Accurate medication reconciliation may require the electronic aggregation of medication data from multiple organizations where care was received or medications dispensed, either via (1) an ongoing collection of data from various organizations into an EHR, disease registry or data warehouse, (2) a real-time distributed query to the various organizations holding the relevant patients' medication history data, or (3) a real-time query to a 3rd-party organization that aggregates patients' medication history data. In each case, an infrastructure is required to securely* transmit clinical data from the source organization to the aggregating organization and to resolve patient-identity discrepancies in the data at the time they are requested or received.

** See section 5.1.1. for discussion of security requirements for meaningful use.*

2. Statewide HIE Planning

Based on the guidance provided by the Strategic Plan and to develop a coordinated approach to HIT adoption that incorporates the views of California's diverse stakeholders, the State enabled a multi-stakeholder planning process by establishing public workgroups, and continues to seek input from the eHealth Advisory Board. The operational planning process was conducted with a commitment to inclusion, transparency and collaboration. Accountability was ensured by:

- utilizing a governance structure whereby all participants are responsible for working with the State and Operations Team to set strategy and adopt policies for HIE operation and subsequent oversight;
- documenting activities via public updates and meeting summaries archived on the State's public website;
- opening participation in workgroups to all; and using online tools to enable open collaboration in the operations planning process and drafting of this Operational Plan.

2.1 eHealth Advisory Board

The eHealth Advisory Board was created in April 2009 to review and provide input on the process and deliverables associated with State implementation of HIE. Co-chaired by Health and Human Services Secretary Kim Belshe and Dr. Paul Tang, Vice President and Chief Medical Information Officer, Palo Alto Medical Foundation, Advisory Board meetings are held in-person at the CHHS offices in Sacramento, CA.

2.2 Operations Team

The State convened an Operations Team to coordinate activities among the workgroups. The Operations team comprised the Deputy Secretary; the Chief, Policy Branch, California Privacy and Security Advisory Board; Chief, Office of Medi-Cal Payment Systems (Medi-Cal's lead for the EHR incentive program), Chairs of the individual workgroups, and consultants engaged by CHHS.⁸ The Operations Team is responsible for coordinating with CalPSAB, the Medi-Cal EHR Incentive Program, workforce training, the RECs, public health programs, and others as appropriate. Other responsibilities included coordinating among the workgroups, drafting the Operational Plan, managing the public comment and review process, and providing progress updates to the eHealth Advisory Board.

⁸ See Appendix 5 for a list of Operations Team Members.

2.3 Workgroups

The workgroups were convened in November 2009 under the authority of the Secretary of the Health and Human Services Agency, and report, on an interim basis, to the Deputy Secretary, Health Information Technology. Four public workgroups were formed, open to all interested participants: Patient Engagement, Vulnerable and Underserved Populations, Finance, and Technical. The primary responsibility of each workgroup during the Operational Planning process was to encourage and coordinate input, draft and review content for the Operational Plan. The workgroups are chaired by volunteers selected by the Deputy Secretary and meet weekly on open conference calls. Minutes of these meetings are maintained and publicly available on the State's ehealth website. Documents and work products are edited and reviewed by all participants via an online wiki. Activities across workgroups, as well as issue resolution, are coordinated by the Operations Team during the interim period before selection of a GE.

Shortly after their creation in November 2009, workgroups created, reviewed, and finalized individual group charters, stating the purpose, principles, and goals of each workgroup⁹. Workgroups also determined the specific inputs into this Operational Plan.

Work processes were conducted on weekly open conference calls, as well as through online communication enabled by the wiki. Required inputs from each workgroup into this Operational Plan included a timeline of activities and milestones for the workgroup throughout the HIE implementation process (2010 – 2015), risk and issue mitigation, cost and staffing estimates for the workgroup over the implementation period, and performance measures and metrics for evaluation of achievement of objectives.

Throughout the operational planning process, workgroup activities were managed by chairs of each group, who led meetings, guided discussion, and coordinated each workgroup's tasks and input into the Operational Plan. Chairs acted as the primary liaison to each workgroup through their role as members of the Operations Team, provided progress updates, brought issues for resolution and mitigation, and ensured coordination with other State and regional activities.

2.3.1 Patient Engagement Workgroup

The Patient Engagement Workgroup's purpose is to develop innovative approaches to engaging and empowering patients and their families through the use of technology that harnesses the HIE infrastructure, and recommend how to incorporate these approaches into the State's HIE services. A

⁹ See Appendices 3 for workgroup charters and members, including biographies of chairs.

guiding principle of the workgroup is to enable each point of care as a point of patient engagement where the patient's physician guides the patient in understanding and participating in the promise of HIE. The goals of the Patient Engagement Workgroup are to:

- Contribute to the Operational Planning process a sound strategy for engaging patients and their families with HIE services;
- Define key elements, a timeline, and resources required for a patient and family engagement strategy, including specific tools to ensure that patients and families have access to and control of their health information;
- Create educational materials for patients and families, design and conduct patient awareness initiatives, and address educational needs to encourage patients' and families' participation as technology and data-enabled partners in the care process as critical to improving the patient's health outcomes;
- Recommend patient and family engagement programs to assist the Governance Entity (GE) and the State to put the \$38.8 million in HITECH grant funding to the best and highest use;
- Develop patient- and family-centric use cases to ensure that implementation maintains a focus on patient involvement and inclusion;
- Define metrics and measurement tools to ensure that patient and family engagement objectives are being met;
- Garner support, consensus and endorsement from California providers, policymakers, consumer advocacy networks, eHealth and Health 2.0 innovators in patient self-management tools, providers, payers and other stakeholders working to foster patient and family engagement with HIE services.

2.3.2 Vulnerable and Underserved Populations Workgroup

The Vulnerable and Underserved Workgroup is charged with ensuring that the design of HIE addresses the specific needs and disparities among specific populations including children in foster care programs, aging and disabled population (including those dual eligible for both Medicare and Medicaid, and those beneficiaries being served through Medi-Cal Managed Care plans), mental health, behavioral health and the uninsured, and incorporate their needs into the operational plan. The Workgroup developed a communication and outreach strategy to ensure that the considerations and disparities among vulnerable

and underserved populations were known and addressed. The goals of the Vulnerable and Underserved Workgroup are:

- Address the specific needs of the underserved and vulnerable populations, and ensure that those specific needs are addressed in the operational planning process so that the HIE works to eliminate disparities in care;
- Ensure that federally defined and California Medi-Cal requirements for addressing the needs of these populations are met to assist the GE and the State to put the \$38.8 million in HITECH grant funding to the best and highest use;
- Ensure that requirements for the expected participants in HIE are incorporated into specific tools and functions developed for these populations; expected participants include: consumers, hospitals, ambulatory care providers, health plans, Health Information Organizations (HIOs), government and others;
- Garner support, consensus and buy-in from California advocacy groups representing these populations;
- Ensure that the HIE needs of the various programs providing critical services to these populations are addressed and met through the HIE services to be developed; and
- Ensure that communication strategies are developed that allow these populations and the programs that serve them to access HIE services.

2.3.3 Finance Workgroup

Recognizing that the creation of a robust HIE infrastructure in California will depend on its ability to secure the financial capital to build infrastructure capabilities and develop ongoing revenue streams to maintain operations, the Financing Workgroup developed financing strategies and sustainability models for operational HIE.

The goals of the Finance Workgroup are to:

- Develop financing strategies that will enable the provision of valuable HIE services, including those that support meaningful use;
- Estimate the cost to achieve HIE throughout the State;

- Develop policy recommendations for financing strategies and sustainability models;
- Develop and compare alternative financial models for sustaining the GE;
- Ensure that the requirements for expected HIE participants are incorporated into and supported by the HIE infrastructure; expected HIE participants include: consumers, hospitals, ambulatory care providers, health plans, HIOs, State and local governments and others; and
- Build support, consensus, and buy-in from California stakeholders around financing strategies and sustainability models for HIE in California.

2.3.4 Technical Workgroups: Technical Advisory Committee and Technical Workgroup

Two workgroups addressed the design and development of the technical architecture of the State HIE. The Technical Advisory Committee (TAC) works to develop the business and clinical processes that the HIE services should support and define the high-level priorities for the Technical Working Group (TWG), which has the decision-making power for the technical architecture and develops the detailed technical requirements. The aim of both groups is to design health information exchange services that support the transformation of California's health care delivery system and the achievement of meaningful use, protect patient data and privacy rights, and is accessible, scalable, sustainable and supportable for and by all exchange participants in California.

The goals of both workgroups are:

- Design a technical architecture, including a core set of shared software services, to enable HIE, which is consistent with and provides connectivity to the Nationwide Health Information Network (NHIN);
- Ensure that federally defined and California Medi-Cal specific meaningful use requirements and functions, including: lab ordering and resulting, e-prescribing and medication management, continuity of care, claims and eligibility transactions, public health, population health and quality reporting are supported by HIE services;
- Prioritize requirements to assist the GE and the State to put the federal HITECH grant funding to the best and highest use;

- Ensure that requirements of the expected participants in HIE are incorporated into the design; expected participants include: patients and families, hospitals, ambulatory care providers, health plans, HIOs, government and others;
- Employ best practices in technical design and development to enable adaptability in a rapidly changing environment, are sustainable in the short and long run and can scale to California's size and accommodate its heterogeneity;
- Develop a technical architecture that is practical; prioritizing what services must be supported in the short, medium and long term, and
- Garner support, consensus and buy-in from California stakeholders.

2.4 Stakeholder Calls and Bulletins

Monthly stakeholder calls, open to the public, are conducted by the Deputy Secretary, and include both a conference call and webinar component. The content of the stakeholder calls includes a review of the objectives of HIE, an update on federal and State activities and funding opportunities relating to HIE, updates from each public workgroup, the Operations Team, and activities of related State agencies' work on privacy and security, workforce development, and other issues. Each meeting concludes with an open Question and Answer session. Audio recordings of the proceedings are posted publicly after each call.

The State also issues periodic "California eHealth Bulletins." The purpose of these bulletins is to communicate the status of California's eHealth initiatives, including the development of this Operational Plan and preparation for submitting proposals to the Federal government to support HIT, HIE and broadband/telehealth programs, and the progress of each.

2.5 Website and Online Collaborative Tools

The State maintains a public website to keep stakeholders across the State informed of the operational planning process: <http://www.ehealth.ca.gov/>. The website provides stakeholder call access information materials and minutes, California eHealth Bulletins, and a link for stakeholders to sign up for public workgroups and participate on the workgroup wikis.

Each workgroup and the Operations Team have separate online portals and online collaborative workspaces where workgroup participants can review and edit shared documents such as the workgroup charter and content for this Operational Plan, create discussions, and provide comments. Workgroup

meetings are announced via online portals and email distribution lists, and meeting materials and minutes are posted.

Review and revision of this Operational Plan was conducted in a multi-stage, open process via online collaboration. In the first stage, each workgroup defined their portion of the plan collaboratively. Then, the draft of the Operational Plan was posted for all members of the public workgroups to review and comment on a wiki that allowed real-time direct editing to the document, as well as active discussion. The plan was reviewed again for additional comment after it was reformatted into a more standard document. After feedback was incorporated, the revised draft was posted in a similar online collaborative workspace for comments by all California stakeholders and the general public. Finally, additional discussion occurred during a joint in-person and online meeting among all workgroup members, all State participants, and the team representing the Governing Entity at the March 11 summit. Comments and feedback were then incorporated into the final Operational Plan.

2.6 HIE Summits

On July 20, 2009, CHHS hosted its first California Health Information Technology and Exchange Summit. The summit was attended in person by almost 200 people; many more participated by phone and webcast. The summit reviewed draft strategic plans for each workgroup and discussed next steps to finalize and publish the plans for public comment.

On March 11, 2010, the State held another Statewide summit to collect input into the draft of this Operational Plan. Workgroup representatives provided short summaries of each section of the Plan, and raised key issues and questions for discussion and resolution in the open forum. The summit was open to the public. The live meeting was augmented by a live online teleconference option for those wishing to participate remotely.

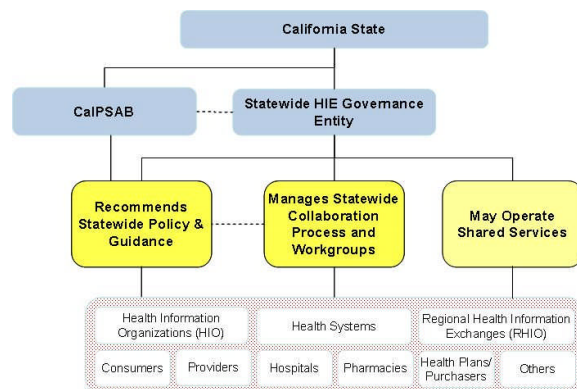
3. Governance

California Senate Bill No. 337, introduced by Senator Elaine K. Alquist Chair, California State Senate Committee on Health, on February 25, 2009, gave oversight authority to CHHS to select and manage a State Designated Entity to govern Statewide HIE based on the vision and goals outlined in the Strategic Plan.

On August 25, 2009, CHHS initiated a Request for Information process to identify the GE. The RFI listed a set of requirements for the responsibilities of the GE,¹⁰ specifying that the GE was to be a public-private not-for-profit entity. On November 20, two leading candidates were asked to submit a joint proposal detailing the formation of a new joint entity. On December 24, 2009, the two responding organizations agreed to submit a joint proposal. On January 11, 2010, that joint proposal was received by the State. **This Operational Plan is a living document, and will be updated on an ongoing basis. This section will be revised at a future time.**

The GE is charged with convening, coordinating, overseeing and managing the implementation of HIE services throughout the State under the State HIE Cooperative Agreement Program. The GE establishes the roles, responsibilities, and relationships between parties; promulgates and oversees activities among stakeholders and across State, regional, and local levels; and oversees implementation of associated accountability mechanisms. The GE formally coordinates activities with the Medi-Cal EHR incentive program, CalPSAB and the California RECs to support meaningful use of EHRs. Importantly, the GE coordinates with the Medi-Cal EHR Incentive Program to form strategies to support California's safety net providers achieving meaningful use of EHRs consistent with federal standards.

The diagram below presents the conceptual view of the relationship among the State, the GE, CalPSAB, and stakeholders.



¹⁰ See Appendix 6 for the Governance Entity Request for Information.

Stakeholder input collected throughout the planning process recommended that the State's role specifically should be to bind participants in Statewide HIE to comply with policies and procedures through explicit contractual obligations. Thus, the State will ask participants to bind themselves contractually to participate in governance and to observe and be bound by technical, business and legal rules for HIE that are adopted as Statewide policy guidance through an inclusive, fair, transparent and collaborative decision-making structure.

In addition, the GE is responsible for ensuring that its activities, workgroups and actions reflect the needs of California's residents. California's residents are diverse in geographic distribution, language, health status, ethnic and racial composition, economic status, education levels, abilities and age. The GE will ensure that objectives, requirements, and structures of health information exchange incorporate these considerations to ensure maximum consumer access and engagement.

As a condition of receiving the State designation, the GE shall comply with all of the following requirements:

- The GE shall be governed by a board with a diverse composition from many varied groups (from consumers to providers to payers) representing geographically different parts of the State (from urban to remote, coastal to valley, and north to south.) The governing board shall include, at a minimum, all of the following:
 - The Secretary of California Health and Human Services or his or her designee,
 - The chair of the Senate Committee on Health or his or her designee,
 - The chair of the Assembly Committee on Health or his or her designee, and
 - At least two consumer representatives, one of whom shall have expertise in privacy and security of health information.
- The majority of the board shall be comprised of nongovernmental employees.
- If the board convenes workgroups or subcommittees, the workgroups or subcommittees shall be comprised of representatives from multiple types of organizations from multiple regions throughout the State. Meetings of any workgroup or subcommittee shall be held in an open, public, and transparent way.

- The GE shall have nondiscrimination and conflict-of-interest policies that demonstrate a commitment to open, fair, and equal participation by stakeholders.
- The State-designated entity shall report to CHHS and the Legislature on its progress and activities at least annually.

The GE will be required to comply with these conditions as part of the State's grant agreement.

3.1.1 Role of the State in Implementation

The California Secretary of Health and Human Services or his/her designee will hold voting positions on the GE's board of directors. An additional seat will be required for a California Administrator such as the Chief Deputy Director of the Department of Health Care Services or the Department of Public Health. These positions on the board enable the State to:

- Directly monitor, guide progress and engage in governance activities,
- Coordinate activities in conjunction with the GE across multiple diverse organizations including the Medi-Cal EHR Incentive Program and State public health programs in order to ensure integration and support of a unified approach to information exchange without duplicating efforts,
- Ensure conformance with State priorities and principles, and
- Monitor the use of funds and administrative processes to support transparency and accountability.

3.1.1.1 Contractual Relationship with the GE

Once the GE is selected, the State will develop a grant agreement with the GE to perform HIE convening, coordinating, and management activities. The GE has a specific evaluation and prioritizing function that focuses on ensuring that progress is being made toward the HIE goals, that course corrections are implemented as needed, and that issues that are beyond the purview of the GE are raised to the attention of State government or other appropriate responsible parties. Because the State is accountable to the federal government and liable for the federal grant requirements, CHHS must ultimately be responsible for all activities of the GE and must ensure that requirements are met. As a result, the GE retains a reporting responsibility to CHHS for at least the duration of the State HIE Cooperative Agreement Program, from 2010 – 2015.

3.1.1.2 Privacy and Security Governance

Integration of privacy and security provisions with other aspects of technical design is fundamental to a successful HIE technical architecture. The governance model recognizes and supports this integration through its structure. The HIE privacy and security governance configuration is a well integrated and organized structure that supports the standardization of privacy and security rules for California health care entities exchanging electronic health information.

As described below, the GE will collaborate directly with California's Office of Health Information Integrity (CalOHII) to ensure standardization of privacy and security policies. The E-Health Policy Branch of CalOHII supports HIE privacy and security initiatives. The key responsibilities of the E-Health Policy Branch are 1) the facilitation of the CalPSAB, 2) the harmonization of State and federal privacy and security laws, 3) the creation of a uniform set of privacy and security rules for California health care entities performing HIE, and 4) the facilitation of demonstration projects. The committee will consider State and national issues, including review of the federal Data Use and Reciprocal Support Agreement ("the DURSA") to align to the extent possible State and federal privacy and security policy.

3.1.1.3 Guideline Development

The HIE privacy and security guideline development process relies upon an iterative methodology that is managed closely by the E-Health Policy Branch. Utilizing CalPSAB's public and private health care industry stakeholders for the evaluation development, preliminary privacy and security guidelines have been drafted. The guidelines were developed using the Health Insurance Portability and Accountability Act (HIPAA) rules and existing California law as the baseline. The guidelines will evolve over time as laws are harmonized, issues are resolved, and testing is completed. The result will be standardized privacy and security rules or "Statewide policy guidance" for HIE. To ensure consistency and trust across trading partners, Statewide policy guidance will be enforced through contract and grant agreements. Much like the federal Data Use Reciprocal Support Agreement (DURSA), all entities that use any of the HIE services developed through the State HIE Cooperative Agreement Program, or who receive grant or contract funds through this program, will be required to adopt these guidelines in their exchange activities.

3.1.1.4 Selection

This Operational Plan is a living document, and will be updated on an ongoing basis. This section will be revised at a future time.

3.1.1.5 Procurement and Management

The GE will perform two procurement cycles in 2010 and 2011 to request proposals, select, and obtain services to provide the functions listed in section 3.1.4.2. Each procurement cycle will include the following steps:

1. Draft procurement requirements
2. Review procurement requirements with appropriate Boards, Committees, and stakeholders, and refine requirements based on feedback
3. Draft Request for Proposals (RFPs)
4. Finalize and release RFPs
5. Review responses to RFPs
6. Negotiate with top responder(s) and award contract(s)
7. Oversee implementation jointly with Evaluator (see section 7, Evaluation.)

The GE's role is to manage the procurement process from end-to-end, by issuing and managing grants, developing legal analyses, and overseeing accounting and budgeting. The GE enforces adherence to Statewide policy guidance through execution of contracts with participants in HIE and shared services and monitors compliance with those contracts by evaluating and assessing progress. The GE is responsible for developing accountability measures for public workgroups, consultants, and organizations participating in HIE services, and for developing or identifying sustainable business models for HIE in collaboration with the Finance workgroup.

3.1.2 Planned Workgroups

In addition to the current public workgroups, Finance, Technical, Patient Engagement, and Vulnerable and Underserved Populations, other public workgroups may be established as the need arises. The GE is charged with continuing to provide a coordinating function by facilitating alignment of Statewide, interstate, and national HIE strategies, and coordinating activities with California REC programs, the Medi-Cal EHR Incentive Program, Public Health, and other related programs and organizations. The GE is responsible for coordinating the activities of the workgroups with those of CalPSAB and ensuring adherence to privacy and security policies with the ultimate goal of promoting consistent and effective HIE policies and practices. The overall goal of the GE and the public workgroups during and after

deployment of HIE services is to support integration of HIE efforts with other healthcare goals, objectives, and initiatives across California and the nation.

3.2 Coordination of Efforts Across All Programs

3.2.1 Coordination with ARRA Programs

The GE oversees coordination and interdependencies between the HIE program and other ARRA programs, including: the Medi-Cal EHR incentive programs, RECs, workforce development initiatives, and broadband mapping and access. As these programs are developed, the GE continues to work with stakeholders to implement ONC program guidance. The State recognizes the need to coordinate these programs to ensure the availability of a sufficient and appropriately trained workforce to support HIE.

3.2.1.1 REC Support and Coordination

Health information exchange and REC services have a set of critical interdependencies. To meet meaningful use, priority providers must perform a set of tasks that require HIE including: e-prescribing, electronic lab ordering and results delivery, sending and receiving electronic messages and patient visit summaries to other providers, etc. To ensure close alignment, CHHS required the three organizations REC applicants (Cal-REC, CalOptima and LA Care) to sign Memoranda of Understanding (MOUs) documenting how all RECs would coordinate activities and share resources across them to develop a common web portal, EHR selection process and other activities. CHHS also required RECs to participate in a Coordinating Council that includes the GE, Medi-Cal EHR incentive program leads, The California Telehealth Network, HIT workforce participants and safety net providers. While the Council does not perform any legal governance oversight, it does ensure that important programs meet regularly to discuss and resolve important issues.

The close coordination will be critical to ensure that the maximize number of eligible providers obtain MU incentives. The following illustrated how these programs will function together:

The GE will define a set of interoperability, privacy and security and other standards and specifications;

The RECs will undertake an EHR product selection and choose a set of EHR vendors, develop master service agreements and incorporate those standards and specifications into the standard contract language; and

For priority providers that already have an EHR and yet do not have the required interfaces, the RECs will ensure that the standards and specifications used are conformant with the GE.

3.2.1.2 Beacon Communities Awards

The Deputy Secretary forged partnerships with the prospective Beacon Communities during the application process to ensure that they were committing to assist the State in advancing HIE policies. In consultation with ONC, CHHS determined that the Beacon Communities could serve as critical test beds for HIE privacy and security policies in the State. By piloting privacy and security guidelines in the market and offering feedback, awarded Beacon Communities will transfer critical data to the GE. The GE will use this information to establish support privacy and security guidelines that are market ready and adoptable, increasing the likelihood of success. It will also use the information from the pilots to inform new, tested policy that may be needed if barriers to safe, secure data exchange are identified

To this end, CalOHII, with the support of their Board, provided a set of policies for which CalOHII and CalPSAB need additional information to inform future decisions and to test implementation strategies for policy recommendations, including those related to consent, authentication and authorization. Each of the Beacon Community applicants partnering with CHHS incorporated the testing of one or more of these policies in their applications and, if awarded, will work closely with CHHS, CalOHII and the GE to implement the pilot and report on their findings.

The Beacon Communities are also expected to build upon the strengths of the public health system. The California Department of Public Health (CDPH) supported Beacon Community grant applications which included local public health departments in their projects. The CDPH plans to work specifically with Beacon grant recipients to understand the complexities of public health reporting requirements through HIE as described in meaningful use definitions. The expectation will be that State level best practices, guidelines, and infrastructure will develop through the grant activities that CDPH can assist in disseminating throughout the State.

3.2.1.3 Telemedicine and Broadband

This Operational Plan is a living document, and will be updated on an ongoing basis. This section will be revised at a future time.

In January 2008 the California Broadband Taskforce concluded that ubiquitous broadband services are “...an integral part of improving the overall health of Californian’s and driving down the cost of care” . The availability of ubiquitous broadband will support the implementation of various technology-

supported health services, including videoconferencing, the Internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

California has moved forward with this vision through a successful grant award of \$22.3 million from the Federal Communications Commission to build the California Telehealth Network (CTN), a high speed broadband network that will allow for the expansion of an eHealth network with an emphasis on rural and underserved populations. This network is scheduled to be built beginning in 2010, connecting over 850 sites Statewide. It is expected that the network will expand to over 2,000 sites through other funding opportunities such as those provided by the ARRA.

In addition to the CTN, California has another broadband network, CENIC, which provides broadband infrastructure to educational and research communities. Many of these facilities could be involved in the provision of clinical education programs.

These networks are a product of California's longstanding commitment and investment in broadband and telehealth. California is a national leader in the development of technology-supported health care, having passed the California Telemedicine Act in 1996. The California Legislature, Governor and voters have demonstrated their commitment to eHealth through the passage of bond funding, legislation and executive orders that support the continued expansion of broadband and eHealth applications.

California also has a HRSA designated Telehealth Resource Center (TRC) that provides program guides, best practices, technical assistance and other supporting services to newly developing telehealth programs funded by HRSA. The California Telemedicine and eHealth Center (CTEC) is California's TRC, one of six designated throughout the country. CTEC has developed a comprehensive set of written program development materials, video education and training, best practice guides, policy guides, telehealth training programs and technical assistance related to telehealth.

The long term vision is to:

Provide the infrastructure to connect the full spectrum of health services in hospital, clinic, schools, homes, community centers, employer-based health sites and mobile applications, ensuring that the user's access and experience of the HIT&E initiatives is that of a consistent, Statewide enterprise.

Provide secure and reliable high speed modern wired, wireless and mobile broadband networks, systems, and capacity that support fully integrated, coordinated and seamless services for patient health care, public health, emergency response and economic development for California residents.

Create a coordinated and integrated system for the delivery of eHealth Services that leverages existing services and resources, and coordinates existing efforts with new State initiatives.

Integrate federally funded Statewide projects and initiatives with efforts for expansion of broadband and development of REC / LECs (Local Extension Centers). Expand existing products and services of the California TRC to provide Statewide telehealth support to the REC (products, templates, tools, training, technical assistance). Coordinate where possible the existing telehealth and eHealth initiatives for Workforce Development and Loan Funds.

These services must enable:

Privacy and Security of Electronic Health Information Exchange

Reliable, modern, high speed wired, wireless and mobile broadband connectivity

Innovative telehealth services

Electronic Health Records / Personal Health Records

Sustainability remains elusive, even for established networks of Telehealth services.

While a variety of funding mechanisms may be available in the short term, sustainability must include a combination of fee structures, grant-type funding and when clearly in the public good, government funding.

3.2.1.4 Workforce Development and Training

Workforce development and training will be critical for all aspects of HIE. Upon ONC's release of funding opportunities related to the Health IT Workforce Development Program, CHHS provided a forum for potential applicants to collaborate and form partnerships. CHHS worked with several of these applicants to convey the State's vision regarding the HIT workforce, one aligned with that of ONC, that there be a coordinated link between high quality, rapid workforce training programs and the RECs, GE, and other employers that can offer on-the-job internship and apprenticeship opportunities critical to quickly expanding the HIT workforce.

To take full advantage of these funds, CHHS has reconvened the Workforce Workgroup that developed the workforce portion of the Strategic Plan and has tasked that group of experts with operationalizing the HIT workforce strategy. The California Health Workforce Alliance (CHWA) has agreed to partner with

CHHS and lead the effort, bringing together the Workforce Workgroup, applicants of the Health IT Workforce Development Program, REC representatives and other employers to foster a coordinated workforce training and job placement program in California. CHWA is a public-private partnership dedicated to the implementation of coordinated, systematic strategies to meet California's emerging health workforce needs. They are committed to linking the proposed training programs with employers and industry stakeholders (including ARRA-funded employers) who can provide input into program design and implementation to meet the needs of the industry.

A specific focus of this effort will be growing the public health informatics workforce. The informatics workforce development program will require staff and skill development both for use as well as a supporting infrastructure. Public health agencies at both the local and State levels will need to augment and/or retrain current staff to be able to support requirements of HIE and meaningful use, in particular at the local level where Public Health agents provide direct patient care. On the county level, Public Health staff provides direct care for certain conditions such as tuberculosis, sexually transmitted diseases, AIDS, well-baby check ups, and immunizations, as well as reviewing charts for other agencies such as California Children's Services. The public health informatics workforce is understaffed for the task ahead. Staff rotation as well as deficiency in skill sets will need to be addressed. Public health will play a critical role in achieving meaningful use requirements through population level activities including assessment, policy development, and assurance in addition to becoming a service provider of registry information, prevalence and incidence data, and interventions for communities. CHHS is aware of the following lead applicants for the ONC Workforce Development Program; other organizations may also have submitted applications:

Community College Consortia to Education Health IT Professionals

Los Rios Community College District
Los Angeles Community College District

Curriculum Development Centers Program

Los Rios Community College District
Coastline College
UCLA
Cal State LA

Program of Assistance for University-Based Training

Claremont Graduate University
UC Davis
San Diego State University

Institutions of higher education and non-profit educational programs around the State have applied for federal funding for workforce development under ARRA, and to date \$31.4M has been received in grant funding to these organizations.

3.2.1.5 Research and Development

CalPSAB is working with Strategic HIT Advanced Research Projects (SHARP) Program applicants to advance research on the security of HIT for the State. CHHS is also encouraging health care venture capitalists to test their innovations within the ARRA-funded programs, so that relevant research findings that reveal cost savings, improved access and/or improved patient engagement tools can be easily disseminated and the innovation adopted more broadly.

3.2.1.6 Public Health ARRA Programs

A variety of public health programs have received ARRA funding to improve the health of the population and deliver services. Examples include funding for Ambulatory Surgical Center Healthcare Associated Infection Prevention Initiative, California Emerging Infections Program and Special Supplemental Nutrition Program for Women, Infants, and Children. Any relevant requirements and lessons for HIE stemming from these programs will be communicated through CHHS and public health representation on the GE Board.

3.2.1.7 EHR Loan Fund Program

Though no loan funds for EHR purchase have been made available to date, CHHS and its partners are prepared to take advantage of ARRA funds that may become available for loans to stimulate EHR adoption and HIE. During the State's strategic planning process, a dedicated workgroup was formed around the possible availability of ARRA loan funds. The group estimated the total need for loans, potential sources of funds, in addition to Federal contributions, and identified the vehicles to operate such a fund. In this model, California RECs would administer a process by which local extension centers (contracted with the RECs) have the opportunity to apply for and deploy working capital for underserved providers, and later repay these loans from the provider's meaningful use incentive payments.

3.2.2 Coordination with Medi-Cal

The California Department of Health Care Services (DHCS) administers the Medi-Cal program that serves 7.5 million beneficiaries. Medi-Cal is the source of health coverage for more than one in ten adults in the State under age 65, one in three of the State's children and the majority of people living with AIDS in California. The program pays for 46% of all births in the State and the care for two-thirds of all

nursing home residents. Medi-Cal payments account for almost two-thirds of all net patient revenue in California's public hospitals. Beneficiaries are almost evenly divided between managed care plans and fee-for-service delivery systems.

The use of health information technology and exchange has been a priority for DHCS for many years. DHCS has implemented online eligibility, online claims submission and adjudication and electronic submission of treatment authorization requests by health care providers. In August 2008, DHCS made system changes to the Medicaid Management Information System (MMIS) to support the electronic connectivity of eligibility files, drug formulary files and medication histories to Surescripts as part of an e-prescribing proof of concept. DHCS administers one of the largest Medicaid data warehouse management decision support systems in the country. The State, legislative staff and the contractor, Ingenix, use the warehouse for many purposes, including oversight of managed care plan activities, investigating fraud and identifying overpayments. In addition, the system is currently being utilized for disease management and care management pilot activities. DHCS recently procured a new contractor to manage and enhance the existing MMIS system. It is anticipated that the new system will provide the opportunity to expand the exchange of health information between Medi-Cal and other entities by 2013.

DHCS' experience with Medi-Cal systems, staff and business activities bring an important component to California's HIE plans and operations. DHCS will coordinate activities between Medi-Cal and State and local public health programs to avoid duplication of efforts and to ensure the integration and support of a unified approach to bi-directional information exchange. DHCS is also embracing the federal Medicaid Information Technology Architecture (MITA) as a vehicle to not only ensure access to enhanced federal funds for future Medi-Cal IT efforts, but also to vitalize strategic planning and implementation at a level of detail that maximizes the opportunities tied to HIT in the coming years. MITA is an enterprise-wide effort for Medi-Cal to improve its abilities to improve patient outcomes and reduce overall costs primarily through taking advantage of improved access to standardized administrative and clinical information. Finally, DHCS is currently pursuing a Section 1115 Waiver that will help leverage the strengths of HIE toward providing quality care and treatment for Medi-Cal beneficiaries enrolled in organized systems of care.

Implementation of the Medi-Cal EHR Incentive Program will provide an unprecedented opportunity for the advancement of health information technology and exchange in California. In June, 2009 DHCS entered into a public/private partnership with the California Health Care Foundation (CHCF) to plan the program. DHCS and CHCF are committed to a partnership throughout the life of Medi-Cal EHR

Incentive Program¹¹. With funding from CHCF, external stakeholders and DHCS staff was engaged in formulating a vision Statement for the Medi-Cal EHR Incentive Program. Over 60 interviews were conducted and an all day visioning session convened in Sacramento with the DHCS Director, the Medi-Cal Director, representatives of the health care community, patient advocates and officials from other States.

On November 19, 2009, CMS approved DHCS' request for \$2.8 million (with 90% federal match) to establish the Office of Health Information Technology (OHIT). DHCS subsequently awarded a contract to the Lewin Group and McKinsey & Company to complete a provider and EHR vendor "landscape assessment." This assessment, identifying approximately 10,000 eligible providers and 316 hospitals in California that will be eligible to apply for Medi-Cal EHR incentive funding, can be found on the OHIT website.¹² If all apply and subsequently meet meaningful use requirements, \$1.4 billion will be infused into the California health care community through this program. In the next phase of the planning process, the consultants will complete a strategic plan for the Medi-Cal EHR Incentive Program, including a campaign plan to educate providers and an implementation plan for the work flow, staffing and resources necessary to implement the program in 2011. It is anticipated the Statewide Medi-Cal HIT Plan will be completed by May 2010.

DHCS and CHHS will continue to work together to ensure the success of the HIE and the Medi-Cal EHR implementation Program. The DHCS Director sits on CHHS' eHealth Advisory Board. Medi-Cal is also represented on CHHS' eHealth Coordinating Council and the Technical Advisory Committee. In addition, there is DHCS staff representation on all of CHHS' HIE workgroups. Reciprocally, the CHHS Deputy Secretary, Health Information Technology, sits on DHCS' Health Enterprise Governance Council and participates in all of DHCS' Medi-Cal EHR Incentive Program planning activities.

3.2.3 Coordination with Public Health

Through multiple program areas, the Department of Public Health works collaboratively with State and federal partners. This shared responsibility is evidenced by the State vital statistics programs who work through the National Association for Public Health Statistics and Information Systems (NAPHSIS) and the National Center for Health Statistics (NCHS) to support the civil registration of births, deaths, fetal deaths, marriages and divorces in the United States. The State Registrar, who is the Director for CDPH, is responsible for the registration of all births, deaths, fetal deaths and marriages in California. As such, there is a critical civil registration component that results in documents that are used for benefits, school

¹¹ The vision Statement can be accessed at <http://www.dhcs.ca.gov/Pages/DHCSOHIT.aspx>.

¹² <http://www.dhcs.ca.gov/Pages/DHCSOHIT.aspx>.

entry, obtaining jobs, and documenting citizenship. There is also a public health component that receives medical information in addition to demographic information for each event that is then analyzed to assess the health of the population, outcome metrics, and care and quality metrics. As the only population data source, the vital records are looked to as a gold standard. In order to capture the entire population, data is exchanged among States so that if a California resident dies in Nevada, California administrators may indicate that on the birth statistics and in State statistics. To improve exchange of information among jurisdictions, NAPHSIS and NCHS have worked with States to develop the State and Territorial Exchange of Vital Events (STEVE) which leverages PHIN-MS services to exchange data. Public health performs similar coordinating activities with almost all program areas, such as the cancer registry, infectious disease surveillance, and food-safety issues and investigations.

The E-Health Policy Branch will maintain active participation on the California eHealth Advisory Board and public workgroups over the next five years. The E-Health Policy Branch staff is represented on the Patient Engagement Workgroup, the Underserved and Vulnerable Population Workgroup, the Financing Workgroup, and the Technical Committee to ensure privacy and security input into the larger HIE picture.

The E-Health Policy Branch will also work directly with the GE. Members and staff of the GE will reside on the CalPSAB and will be encouraged to participate in Committees and Task Groups. Reciprocally, members and staff of the CalPSAB will participate on technical infrastructure workgroups of the GE. This structurally defined information sharing will ensure privacy and security input into the technical design and curb redundancies in like efforts.

3.2.4 Coordination with Other State Programs

CHHS will coordinate with many of California's health care stakeholders through meetings, internet postings, correspondence, and other updates and among federal and State government entities, including:

- Alcohol and Drug Program;
- California Public Employee Retirement System;
- Department of Developmental Services;
- Department of Health Care Services;
- Department of Managed Health Care;
- Department of Public Health;

- Department of Mental Health;
- Indian Health Services;
- Medi-Cal;
- Managed Risk Medical Insurance Board;
- Office of Statewide Health Planning and Development; and
- County-operated and administered behavioral health agencies.

3.2.5 Coordination of Services for Vulnerable and Underserved

Coordination of services and IT efforts across State programs, particularly for vulnerable populations, is critical for the successful implementation of an effective HIE. For example, coordination of HIE efforts with the Department of Social Services (which is in the process of procuring a new Child Welfare Services Case Management System) and the Child Welfare Council (which is developing and reconciling policies, including data and privacy policies, across systems that serve children in foster care) will be necessary to ensure consistent policies and interoperable systems to improve service delivery and outcomes for children in foster care.

3.2.6 Coordination with Federal Efforts

The Centers for Disease Control and Prevention (CDC) Public Health Information Network (PHIN) is a national initiative to improve the capacity of public health to use and exchange information electronically by promoting the use of standards and defining functional and technical requirements.¹³ Public health programs must comply with PHIN requirements for systems which are specified in grants as well as part of standards necessary for reporting to the CDC for a variety of program data. Although requirements continue to change over time, the principal is the use of standards based architecture, vocabularies, messaging, and data standards to facilitate the exchange of data and information from local to State to national public health agencies. This public health experience in creating electronic exchanges may be leveraged in the national HIE efforts. In addition, it will be critical for the CDC PHIN requirements to align with ONC requirements related to HIE including the NHIN, Healthcare Information Technology Standards Panel (HITSP), EHR Certification, and meaningful use requirements.

¹³ <http://www.cdc.gov/phinf/about.html>

3.2.7 CHHS Coordination with Other States

California borders Arizona, Nevada, and Oregon. Like its border states, California faces many barriers to the development of HIE. Recognizing the barrier to interoperability posed by varying state health information privacy laws, efforts will be made to harmonize the disparate requirements of our neighboring states. While California does not have particularly dense populations along its state borders, health care providers, especially large hospital systems, have a significant presence in neighboring states. These institutions are interested in participating in programs that are consistent across state lines and do not require distinct and inconsistent policy guidance and rules. The State will continue conversations with policymakers, the public, and private institutions from our own and neighboring states.

The E-Health Policy Branch is also connected to the National Governors' Association's (NGA) discussions on strategies for advancing interstate HIE. The E-Health Policy Branch will continue to monitor NGA's work on alternative policies to remove barriers to interstate HIE. Future demonstration projects will be expected to test policies that facilitate interstate HIE.

The emerging NHIN Direct model may prove a valuable resource in addressing both inter- and intra-state HIE, and the State actively seeks opportunities to participate in pilots and demonstrations in these and other efforts to develop interstate compacts to enable cross-border HIE. At the HIMSS 2010 Interoperability Demonstration, three California HIOs at the request of CHHS - Santa Cruz, EKCITA and LBNH - took part in a successful "Coordinating Care across California" NHIN demonstration. We expect to participate in demonstrations and pilots using live patient information once the NHIN Connect infrastructure is in place.

4. Landscape and Capacity Assessment

4.1 CA landscape: The Varied Characteristics of HIE Stakeholders and their Relationships

The basic EHR adoption rate among California providers ranks above the national estimate; yet the State has a long way to go before comprehensive adoption is realized.¹⁴ A California Primary Care Association (CPCA) survey from August 2009 found that at least 20% of community clinics and health centers had and were actively using EHRs, another 10-20% was actively pursuing EHR adoption, and 30% intended to start pursuing an EHR when the incentive program begins. Similarly, among individual physicians, California physicians reported greater use of EHRs than the national average with 37% of physicians reporting EHR use in comparison to 28% nationally.¹⁵ The majority of community clinics have some form of health IT in place, most commonly in the form of diabetes and immunization registries.

California's current HIE efforts fall broadly into two categories: (i) large health systems, affiliated providers and ancillary services implementing integrated EHRs, and (ii) community-driven efforts that aim to ensure ubiquitous availability of data within a region or across the State.

California's large, diverse health care delivery system is characterized by provider organizations of widely varying sizes, including very large (Kaiser-Permanente), large (Sharp Healthcare), medium-sized (Palo Alto Medical Foundation), and small (small and solo physician practices) providers. Outpatient providers in a community may be tightly integrated (e.g., via integrated delivery networks), loosely affiliated (e.g., in Integrated Practice Associations, or IPAs), or entirely independent. Hospitals may be part of regional, Statewide, or multi-State chains or they may be independent local facilities. Hospitals and community outpatient physicians may be tightly integrated in combined business entities (such as an Integrated Delivery Network, or IDN, like Kaiser-Permanente), or they may be related only by virtue of physician admitting privileges. Provider organizations that are part of larger commercial entities may be well-capitalized and capable of sophisticated infrastructure projects, whereas independent provider organizations or organizations treating underserved populations may be thinly capitalized and less able to develop and support complex infrastructures. In addition, the Veterans Administration, Department of Defense, and Indian Health Service also operate substantial facilities within the State.

With respect to ancillary services, large clinical laboratories with national data centers operate in California, as do smaller regional labs and local hospital labs. National pharmacy chains have facilities

¹⁴ California Health Information Technology Study: Input to the California Health Data Exchange Roadmap, Accenture, January 2007. See <http://www.hmohelp.ca.gov/library/reports/news/CA%20HIT%20Study%202007.pdf>

¹⁵ Ibid.

across the State, but small independent pharmacies also operate in their local communities. Imaging centers, urgent-care facilities, surgical centers, surgical hospitals, and dialysis centers are similarly diverse in their degree of “horizontal” integration (i.e., chains versus independents) and their degree of “vertical” integration (i.e., their business relationships with hospitals, community physicians, employer groups, and other entities).

Healthcare in California is funded through a similar mosaic of payment mechanisms. National, State-wide, and regional commercial insurers operate in California. State and local governments finance care for the underserved through a variety of mechanisms, including Medi-Cal (fee for service and managed care), Healthy Families, and the County Medical Service Program, as well as a separate mechanism for managing prisoner health. Medicare finances care for the elderly population. Insurance-payment models include network-based fee-for-service (Preferred Provider Organization, or PPO), network-based capitation (Health Maintenance Organization or HMO), and indemnity, as well as a wide variety of payments at facilities including percent of billed charges, case rates, per diem charges, and hospital capitation. Delegation of risk and other insurance functions via HMOs is more common in California than most other States. Medi-Cal and Medicare delegate risk and claims-payment functions to commercial insurance carriers through Medicare Advantage and other programs. Commercial insurers delegate risk and claims-payment functions to contracted IPAs or medical groups. IPAs delegate risk to their member providers.

A patient-centered health care system will necessitate HIE across all of these types of organizations, regardless of their sizes, relationships or existing HIT capabilities.

4.2 Gap Analysis for Achieving HIE in California: What’s Currently Missing?

The relatively low penetration of EHRs in outpatient practices and hospitals is an obvious barrier to the achievement of HIE for meaningful use. However, in assessing the gaps in HIE capabilities required for meaningful use, the TAC and TWG anticipate that providers will be using certified EHRs or EHR modules, because otherwise they would not be eligible for meaningful use incentives.

The list below highlights some of the prominent gaps in HIE capabilities needed for meaningful use in 2011, as defined in the recently released NPRM and Interim Final Rule for Standards for Electronic Health Records (IFR):

- Between 50% and 60% of outpatient labs in California are performed by either LabCorp or Quest Diagnostics. The rest are performed by over 17,000 hospital, regional, public health and provider office labs, none of whom represent significant market share. Many of these

hospital and regional labs are not prepared to send structured electronic lab results to outpatient physicians.

- There is no universally trusted framework for identity management and authentication of the principals participating in HIE transactions. Where trust relationships exist, they exist only (1) among principals within the same enterprise and (2) among principals in enterprises that have bi-lateral information-exchange agreements or (3) among principals in enterprises that participate in a regional HIO with a trusted identity-management framework.
- Many eligible professionals practicing in small provider organizations (including those with EHRs) lack the ability to provide patients' access to their health data through a "tethered" PHR (i.e., one that is tightly integrated with the organization's EHR).
- Many eligible professionals practicing in small provider organizations lack the ability to aggregate data sufficiently to generate patient lists or report ambulatory quality metrics from EHR to support the disease-management and quality measurement requirements of meaningful use.
- Many of California's 11 immunization registries lack electronic interfaces and the required security provisions to accept immunization data directly from EHRs.
- The public health department's CalREDIE infrastructure for collecting reportable lab data (ELR project) and syndromic surveillance data (CMR project) is not yet operational Statewide.
- Most provider organizations and ancillary organizations do not have technology in place on site or via external service providers or regional HIOs to generally participate in meaningful use.
- Some regions in the State continue to operate in an extremely competitive environment for healthcare services, limiting their ability or desire to cooperate in HIE activities.

4.2.1 Current HIE Capacity in California

California's existing infrastructure and available resources vary in stage of development achieved. In California, multiple uncoordinated HIE efforts have developed over the past 15 years as regional initiatives. Of these efforts, only three are exchanging clinical data today. The remaining efforts are focused primarily on organizing, fundraising, and piloting their solutions.

4.2.1.1 Regional HIOs

Currently, California has a small number of Health Information Organizations (HIOs) in several regions of the State (See Table 3). These efforts are at different stages of maturity and address various types of HIE goals. Although several are operational and provide valued services, none as yet encompass all of the health care organizations in its respective region, nor provides all of the HIE capabilities required to meet the meaningful use criteria. As these organizations further focus their efforts on supporting meaningful use goals, they will support HIE in their regions more extensively and perhaps expand as the demand for HIE across enterprises increases with the Medicare and Medi-Cal incentive programs. The technologies used in some of these HIOs may provide models or actual solutions for HIE, or these regional HIOs may need to change and evolve to comply with CalPSAB HIE guidelines and other evolving State and federal rules. For the time being, however, only a minority of eligible providers in California have access to HIE services through a regional HIO.

Table 3. Regional Health Information Organizations in California

HIE	Year	Region	Org	Technology	Operational*	NHIN	Clinical Priorities	Financing to Date	Sustainability Model
Access El Dorado (ACCEL)	2004	El Dorado County	Unincorporated	Federated	Public health, mental health, 7 clinics, 2 hospitals	NA	Care coordination; public health, medical home	Grant, county, First 5, hospitals	In development
EKCITA	2004	Eastern Kern County	501(c)3 (2009)	Hybrid open source system	3 clinics; 2 private practices; 1 hospital	NA	Diabetes & Regional public health issues	Grant	Minimum volume of users
Health-e-LA	2004	Los Angeles County	Unincorporated	Federated	NA	NA	Safety net	Grant, private	In development
Long Beach Network for Health	2003	Long Beach	501(c)3 (2007)	Hybrid federated model	NA	Yes	ED & Patient safety	Grant	Minimum volume of users
OCPRHIO	2007	Orange County	Unincorporated	Federated	NA	NA	ED	Grant	In development
Redwood MedNet	2003	Mendocino, Sonoma, Lake Counties	501(c)3 (2005)	Federated with decentralized network	30 providers, 8 practices, 5k transactions/month	Yes	Clinical data; Lab results, radiology, ePrescribing	Grant and private	Cooperative health data access service
Santa Cruz HIE	1995	Santa Cruz	IPA & hospital based	Push model; vendor outsourced	Local hospital; county clinics; IPA 90k transactions/month	Yes	Clinical messaging; results delivery; eRx	IPA support	Hospital & IPA contributions

4.2.1.2 Other Existing HIE Infrastructure

4.2.1.2.1 Surescripts

The Surescripts prescribing network is potentially an important component of the HIE infrastructure for electronic prescribing in the outpatient setting. The network currently reaches approximately 75% of the retail pharmacies in California for electronic prescriptions and renewal requests. Coverage varies somewhat by metropolitan statistical area (range: 68% to 100%). The Surescripts network provides a way for retail pharmacies that are parts of large chains to connect, but offers significantly fewer connective

services for independent pharmacies. Hence, areas with more independent pharmacies generally have less access to large e-prescribing networks. Notably, in the Los Angeles-Riverside-Orange County network, nearly a third of the 3,000 retail pharmacies are not yet connected to the Surescripts network. Depending on the geographical clustering of connected and excluded pharmacies, there may be areas in which eligible providers with EHRs are not yet able to submit prescriptions electronically via the Surescripts network.

The Surescripts network may also be an important facilitator of medication reconciliation, as medication dispensing and claims data from participating pharmacies and PBMs are aggregated within the network and made available to authorized health care providers. This service provides a potential means for viewing outpatient medication histories across sites of care. As with e-prescribing, the effectiveness of this resource is affected by its degree of coverage among pharmacies and PBMs, which is not yet universal.

In addition to coverage gaps, the Surescripts network currently has a few technical limitations. These issues include difficulties in directing prescription-renewal requests to providers that practice at multiple sites and occasional challenges in matching patient identities when retrieving complete medication-history data.

The inclusion of Surescripts in this plan is not an endorsement by the State, but rather recognition of the value that this network may bring toward the successful implementation of this Operational Plan.

4.2.1.2.2 HIE Infrastructures of Large Provider Organizations

Certain provider organizations in California are already well integrated and achieve HIE within the scopes of their enterprises. Kaiser Permanente is the largest and best example of such provider integration. The Kaiser delivery system recently completed a large EHR infrastructure project that enables individual providers to share and exchange information with each other, as well as to prescribe electronically, receive test results electronically, and provide patients access to their own health data through a web portal. Within the Kaiser delivery system, therefore, much of the infrastructure necessary for meaningful use already exists.

A number of IDNs have also developed HIE capacities that allow their constituent physicians, hospitals, and ancillary service providers to exchange health information electronically today. Some systems engage in collective purchasing of EHR technology and have adequate capital budgets to integrate their EHRs with each other, with their hospital systems, with their ancillary services, and with other data sources. Although few of these IDNs achieve sufficient HIE to support all of the meaningful use goals,

they are relatively well positioned to support HIE through their abilities to dictate standards within their organizations, build customized data interfaces, and operate internal infrastructures for authentication and access control.

A number of more loosely affiliated, community-based provider organizations in California, such as IPAs, have also developed some HIE capabilities. IPAs provide additional HIE resources, such as data interfaces to local hospitals, administrative web portals that facilitate eligibility checking (especially for capitated patients), and patient web portals that provide patients access to their health information and messaging with their providers. Although no specific patterns of integration exists across the many different and diverse IPAs in California, many are providing some or all of these capabilities, with plans to expand these services as the meaningful use incentives create increased demand for HIE.

4.2.1.2.3 Commercial Infrastructure Components

Beyond the HIE infrastructure that provider organizations have built or purchased for their specific use, a number of commercial resources exist that can facilitate HIE required for meaningful use in the future. Several are listed below.

- *Untethered PHR systems (e.g., Google Health, HealthVault).* These systems may play a role in providing patients with access to their own medical information under the meaningful use requirements to the extent that providers' EHR systems can securely export such data to the accounts that patients maintain in these systems. Standards for specific activities and services enabled by PHRs will need to be developed before this is likely to occur on any large scale. This approach may be valuable for providers who do not have the capacity to operate their own patient web portals. Several provider organizations have implemented or are exploring this strategy today.
- *Insurance clearinghouses for Electronic Data Interchange (EDI) transactions (especially claims submission and electronic remittance advice).* These clearinghouses remain the prevailing mechanism for providers to electronically transmit claims to payers. They serve the purpose of aggregating claims submissions from many small provider organizations and forwarding them to payers, which obviates the need for payers to maintain direct connectivity with thousands of physician practices. At least a dozen clearinghouse vendors currently provide this service in California. One potential advantage of the expansion of EDI services to include clinical data is that these organizations have existing provider relationships and the

payment for the financial transactions may be sufficient to cover some or all of the costs of the clinical transactions.

- Payers' portals for web-based administrative transactions; specifically, eligibility inquiries.*

All of the major payers in California, including Medi-Cal, provide web portals for submitting eligibility inquiries. These portals provide basic eligibility information regarding a member's enrollment status. Some of the portals provide more detailed information about eligibility, including specific covered benefits and/or patient-specific deductible balances. However, this infrastructure for electronic eligibility checking remains imperfect because (1) multiple discrete data elements are required to uniquely identify someone and avoid false positive matches in the payer's enrollment database, and (2) many payers do not provide all of the needed eligibility and benefits information via their web portals.

4.2.1.2.4 Immunization Registries

Nine regional and two county immunization registries currently operate in California, collectively known as the Statewide Immunization Information System (SIIS). Together, these registries cover the entire State, although they operate independently and there is no ability to search across multiple registries at this time. However, a project is currently underway to aggregate data from the registries into a centralized repository, which providers will be able to query when they cannot find information on a patient in their local registries. New immunization records will continue to be entered into the regional registries.

Figure 1 Immunization Registries in California



The California Automated Immunization Registry (CAIR) software is used for 6 of the 11 registries, with the remaining registries based on other software systems (see Table 4). Notably, most of the 11 registries are web-based portals that require manual interaction and have no capabilities to interface with EHRs or HIE.

Table 4. Systems and Interfaces for Immunization registries in California

Region	System Used	User Access
Bay Area Regional Immunization Registry (BARR)	CAIR	Web
Central Coast Immunization Registry (CCIR)	CAIR	Web
Central Valley Immunization Information System (CVIIS)	CAIR	Web
County Registries: Imperial County	County-Specific	Web
Contra Costa Automated Immunization Registry (CCAIR)	County-Specific	Client Server
Immunization Network of Northern California (INNC)	CAIR	Web
Los Angeles-Orange Immunization Network (LINK)	CAIR	Web
Regional Immunization Data Exchange (RIDE)	Region-Specific	Web
San Diego Regional Immunization Registry (SDIR)	Region-Specific	Web
Shots for Tots KIDS Regional Immunization Registry	CAIR	Web
VaxTrack Regional Immunization Registry	Region-Specific	Client Server

4.2.1.2.5 Public Health Surveillance Resources

The California Department of Public Health is currently implementing the California Reportable Disease Information Exchange (CalREDIE) project. CalREDIE will support the electronic submission of lab results for reportable diseases via the Electronic Lab Reporting (ELR) system, as well as web-based Confidential Morbidity Reporting (CMR). Both ELR and CMR through CalREDIE specifically target the eighty (80) reportable diseases and conditions as cited under Title 17 of the California Code of Regulations.

The CalREDIE Project begins a three-month, three-county pilot phase in January 2010, including both ELR and CMR. In pilot, ELR includes both a manual and an electronic method to receive messages, such that lab results can be entered manually and sent electronically. However if a lab can produce an HL7 message, the CalREDIE system can consume the message.

The CalREDIE system is scheduled for completion by the spring of 2011. Once fully implemented, ELR will provide for electronic data submissions from approximately 2,200 commercial labs (hospitals, reference, public health, etc.) and 15,000 licensed physician operated labs.

State legislation (AB 2658) requires labs to electronically transmit lab reports to the State of California. This requirement is referred to as “lab readiness” for which labs have already begun work to prepare and

map lab tests and results to standard terminologies such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine (SNOMED) and subsequently construct standard Health Level 7 (HL7) messages for transmission.

At the local level, more than half of the 61 local public health jurisdictions are engaged or have previously engaged in syndromic surveillance data collection. Data sources vary widely, but predominantly include Emergency Department (ED) data from chief complaint or ICD-9 diagnosis. Other data sources include school absentees, sentinel providers, pharmacies, and labs. Some syndromic surveillance data are submitted electronically, but this varies widely by data source, jurisdiction, and surveillance platform or solution. For example, ED data often originates in billing systems, which tend to be automated more readily by large providers. CDC offers surveillance tools to analyze these data, including BioSense, ESSENCE, Real Time Outbreak Disease Surveillance (RODS), Early Aberration Reporting System (EARS.) Commercial offerings include SYRIS, FirstWatch, Reddinet, and EpiCenter.

4.2.1.2.6 Health Data Standards Infrastructure

The technical architecture for Statewide HIE services will use the following existing health data standards:

Lab Reporting: Although many versions of HL7 are used currently for reporting lab results to EHRs in California, an effort is underway to standardize lab reporting based on the EHR-Lab Interoperability and Connectivity Specification (ELINCS) implementation guide, which was developed by the California HealthCare Foundation and HL7. Although ELINCS is used in only approximately 50 lab interfaces today, its use continues to grow and it is supported in California by a number of lab service providers, including Quest Diagnostics and LabCorp. By the end of 2010, Quest Diagnostics will offer lab reporting based on the ELINCS standard to any of its clients in California, utilizing Quest's national result-reporting hub and web-services protocols.

Administrative Simplification: There is nearly universal support for the HIPAA X12 4010 administrative transactions among commercial payers in California. In particular, these payers support the 270/271 transaction for electronic eligibility checking and 837 transaction for claims submission, as required by the EHR-certification criteria for meaningful use. Although only 50% of the private payers currently support the Council on Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) Phase-1 rules, which are also required for meaningful use, two-thirds have indicated that they are planning to support the Phase-1 rule within the next 12 months.

Clinical Summary: Many of the EHR vendors currently used by Eligible Providers in California are expected to be using certified EHRs which support the HL7 Continuity of Care Document (CCD) or the American Society for Testing and Materials Continuity of Care Record (ASTM CCR) document standards for exporting and importing clinical summaries. At least 80 ambulatory EHR products are now certified to this level. Fifteen products also support the CCR format for structured document exchange. Although the CCD and CCR standards are just starting points towards semantic interoperability of clinical summary data, they are sufficient to satisfy the meaningful use criteria and are already supported by many of the products likely to be used in California.

4.2.1.2.7 Network Infrastructure

According to the 2007 California Broadband Task Force study, 96% of California residences have access to residential commercial broadband services such as DSL and cable. Based on these findings, the TAC and TWG presume that roughly the same percentage of health care providers has access to broadband. Areas lacking coverage appear primarily in rural and isolated regions of the State, where population density is low. Even in these areas, however, T-1 grade network service is available, although at much higher and often prohibitive price.

With the goal of narrowing the urban/rural gap in residential broadband coverage, the California Telehealth Network is a Statewide initiative to bring network services sufficient for telehealth applications to all health care facilities. This project, which is largely subsidized through a 3-year Federal Communications Commission (FCC) grant, plans to build a private network with sufficient bandwidth (1.5 Mbps) and specialized capabilities to support real-time video-conferencing and other telehealth applications. A secondary goal of this project is to bring broadband-grade service to health care facilities in rural areas at a more cost-effective price than currently offered through the commercial marketplace.

5. Technical Infrastructure Background and Design Approach

To help define the requirements for the HIE architecture, members of the TAC completed a survey describing their current HIE capabilities, the technical resources they use to achieve these capabilities, and gaps in resources that impede or prevent their ability to achieve HIE. Although the TAC membership represents only a very small subset of the broader stakeholder community in California, the members of the group were able to share diverse views on HIE design.

The straw man architecture described here was defined by the TWG, based on general requirements proposed by the TAC and based on the TWG members' own knowledge of technical requirements for HIE. The design approach begins with proposing this high-level architecture and a number of specific architectural components as a starting point for further discussion. Hence, the design expressed in this draft document is by no means the only design or necessarily the best design for the future HIE architecture. Comments and input on this document and future versions of it will inform that ultimate design even as this operational plan is implemented.

5.1 Business and Technical Requirements

The HIE design was informed by a set of general principles and guidelines, as well as a set of specific requirements coming from the meaningful use requirements of the federal government. In addition, the design is intended to address gaps between existing infrastructure for HIE in California and the needs of stakeholders to achieve meaningful use and other healthcare improvement goals.

5.1.1 General Principles and Guidelines

The following list represents high-level requirements that provide guidance for the conceptualization and design of an HIE infrastructure in California.

- The health information exchange capabilities that are needed to ensure compliance with the federal government's meaningful use criteria should inform prioritization of the functional requirements for the technical architecture and the shared services that will be developed. However, although priorities, the technical infrastructure and services should not be bounded by the meaningful use criteria, and services provided by the HIE should be self-sustaining and help offset the costs of building additional value-add services.
- The HIE services should support means for provider organizations of all sizes, in all locations, and serving all populations, including the vulnerable and underserved, to achieve meaningful use.

- The HIE services should complement and support, not impede, the core business and clinical processes of the intended providers and consumers of HIE services.
- The HIE services should facilitate HIE where existing HIE resources are lacking or insufficient to ensure that effective and affordable HIE services are available Statewide. Existing investments in HIE infrastructure should be leveraged, and HIE services should not disrupt or displace existing, effective HIE resources that are compliant with State and Federal requirements providing they comply fully with the State's HIE governance and technical requirements.
- The near-term adoption and use of these HIE services should be balanced against the requirement to have a robust long-term solution. The architecture should be flexible enough to enable a process of continuous improvement to address technology changes, new security threats, and developing technical specifications, requirements, and innovations.
- Patients and their families should be considered among the consumers and primary beneficiaries of HIE services and the meaningful use of HIT, and their needs should guide aspects of the design.
- The HIE infrastructure should be secure with respect to ensuring the identities of counterparties, transmitting health information such that it cannot be disclosed to unauthorized parties or modified in transit, and being in compliance with all applicable regulations and laws (including those CalPSAB guidelines that are ultimately adopted by CHHS).
- It is not sufficient for the HIE infrastructure to actually be secure. It must also be *perceived as secure* by California stakeholders, including health care providers and the general public. The HIE infrastructure must be paired with appropriate policy and procedure infrastructure to develop the trust required to be used by California stakeholders, including health care providers and the general public.
- The technical and security requirements of the HIE services must be consistent with and should support participating entities' compliance with privacy and security requirements.
- Use of the shared services developed under the State HIE Cooperative Agreement Program should be voluntary. Any stakeholder can choose to use the resources of their own enterprise, a regional HIO, or any other entity to achieve HIE.

- Use of the shared services developed under the State HIE Cooperative Agreement Program should be available to any healthcare participant, subject to the technology requirements, operating rules and fee requirements of the services, and restrictions or requirements of HIPAA and the HITECH provisions of ARRA.
- The design shall support interoperability with the NHIN as one emerges and with the HIE infrastructures of other States.

Security Requirements of Certified EHRs: The meaningful use criteria within the NPRM specify that eligible professionals and hospitals use certified EHR technology for HIE. The security requirements for EHR certification, as currently specified in the Interim Final Rule (IFR), include the following provisions:

1. Health information must be encrypted when in transit through the use (at a minimum) of transport-level security mechanisms, such as Transport Layer Security (TLS) or Internet Protocol Security (IPSec.)
2. It must be possible to verify that exchanged health information has not been altered in transit through the use of a secure hashing algorithm.
3. Transactions must contain sufficient identity information about the sending party (whether that party is providing health information or requesting health information) that the receiving party can make access control decisions and produce detailed and accurate security audit trails.

5.1.2 California Privacy and Security Requirements

CalPSAB has formulated a set of recommendations regarding privacy and security guidelines for exchanging health information under the State HIE Cooperative Agreement Program. The guidelines that are accepted by the Secretary will become binding requirements for all entities that exchange health information using resources of the State HIE, via execution of contracts and grant agreements between the GE and participants in HIE.

The recommended guidelines are currently in draft form, but it is expected that many will be accepted by the Secretary. In certain cases, these guidelines go well beyond the requirements for HIE set forth in the meaningful use NPRM and in HIPAA, so it is important to consider them in planning an HIE infrastructure for California.

Notable guidelines proposed by CalPSAB include:

- *Allowable uses and disclosures of PHI via HIE:* Uses and disclosures of individual health information for transmitting through an electronic health information exchange initially are limited to (1) clinical treatment where a health care provider/individual relationship exists and (2) mandated public health reporting purposes. This guideline applies to an independent health information organization, as well as to two separate health care organizations who exchange individual health information without the use of a third party organization.
- *Patient Consent to transmission of their PHI via HIE:* An Opt In policy must be obtained to transmit individual health information through an electronic health information exchange for all other purposes before the information may be exchanged electronically. CalPSAB is reviewing opt-in policies subject to federal and State law and in consideration of the State HIE Cooperative Agreement Program with ONC, and the features of the opt-in policy may change.
- *User authentication within an entity:* An entity shall authenticate each authorized user's identity prior to providing access to individual health information. An entity shall authenticate each user to the level of authorized access that complies with the entity's level of trust agreement with the external exchange entity. An entity that authenticates users attempting to access individually identifiable health information remotely from an unsecured location or device, shall require National Institute of Standards and Technology (NIST) Level 3 authentication in which the data requester must establish two factors of authentication. For example, if Entity A requires two-factor authentication to allow disclosures of PHI to Entity B, Entity B will need to use two factor authenticate for its own users, at least when requesting information from Entity A.]
- *Entity authentication within a "trust network":* If an entity is participating in a trust network health information exchange, the trust network shall manage entity authentication for those participating on the trust network, and an entity shall manage user authentication only for those entities participating on the trust network. If the user authentication process is across multiple systems or entities, an entity shall implement the agreed upon authentication process as specified by the requesting entity among the participants in the trust network.
- *Authorization and access control:* An entity shall use the following access control attributes to determine if a user is authorized to access requested information in a way that corresponds

to, and is compliant with, the data use agreements governing such access and as it aligns with State requirements:

- a) Data Source;
- b) Entity of Requestor;
- c) Role of Requestor;
- d) Use of Data;
- e) Sensitivity of Data;
- f) Form of Data (or, how the data is provided);
- g) Consent Directives of the Data Subject

An entity that acts as a data requestor shall execute the authorization process at the location agreed upon in the data use agreements governing that exchange. The data requestor shall pass the authentication and authorization to the data supplier as a single message if so designated by the data use agreement.

5.2 The Proposed Architecture

5.2.1 Definitions

The definitions below help to describe the elements of the proposed HIE architecture and how they may interact. These definitions are not necessarily authoritative across all contexts. Certain of the definitions are based on the consensus definitions of ONC¹⁶ whereas others are *ad hoc* definitions intended specifically to explain the HIE architecture described in this document.

HIE: The electronic movement of health-related information between *principals* (see definition below).

Principal (aka “actor”): The individual or entity that is the original sender or the intended recipient of exchanged health information. May be a person, an enterprise, a part of an enterprise (such as an emergency department), an application, or a data repository (such as an immunization registry). If denoting a person, a principal may be a health care professional or an administrative professional at a health care enterprise. Examples of principals are: a physician, a physician practice, a hospital, a care manager, a health plan, a pharmacy, an immunization registry. Operationally, principals are the entities

¹⁶ See http://healthit.hhs.gov/defining_key_hit_terms.

that initiate HIE transactions or the entities to which HIE transactions are directed. Note that principals are not equivalent to the “nodes” or “end points” on a network. Principals use such nodes to send or receive information.

Counterparty (aka “data-trading partner”): The “other” principal with whom a specific HIE transaction is conducted. May be an individual or an entity.

Legal Entity: A business entity that assumes responsibility for safeguarding the patient health information under its control and for managing in a secure manner the exchanges of patient health information in which it participates. Legal entities may be physician practices, hospitals, pharmacies, health plans, health information organizations, etc. The responsibilities of legal entities include (1) reliably authenticating their users and applications (i.e., *principals*) when they request access to PHI that is controlled by other legal entities, and (2) reliably authorizing access to the PHI they control when requested by other legal entities.

Enterprise: A discrete business entity that controls in a “top-down” and centralized fashion the selection, purchase, and management of its H.I.T. resources, including the manner of interoperability among those resources. Enterprises may be healthcare provider organizations, public health agencies, payers, etc. An enterprise is usually a *legal entity* (as defined above), although it could be a collection of multiple legal entities (e.g., an IPA that purchases and manages the information systems of its constituent practices) or just part of a legal entity (e.g., a hospital clinic that controls its own I.T. infrastructure). The key attribute of an enterprise is internal control over its I.T. resources, such that the enterprise can achieve *internal* HIE without necessarily having to agree on communication protocols, messaging formats, etc. with other business entities.

Health Network Node: An addressable network node that may be the source or the recipient of an HIE “transmission.” Health network nodes may include EHRs, lab information systems, PHRs, , interface engines, etc. Health network nodes are not equivalent to principals or legal entities. For example, in the electronic delivery of a lab result, the principals are the laboratory and the physician, the legal entities are the hospital in which the lab resides and the medical group in which the physician practices, and the health network nodes are the hospital’s interface engine and the physician’s EHR.

Health Information Organization (HIO): An organization that oversees and governs the exchange of health-related information among principals. HIOs may include *regional* HIOs (see below), IPAs, or other private non-profit, private for-profit, or government entities that oversee and govern HIE. HIOs often provide *HIE Services* (see below).

Regional Health Information Organization (Regional HIO): An HIO that brings together health care stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and health care in that community.

HIE Service: **Any information system** that facilitates HIE, along with its related standards, policies, and processes. HIE services may be provided by private non-profit, private for-profit, or government entities, including HIOs and commercial vendors.

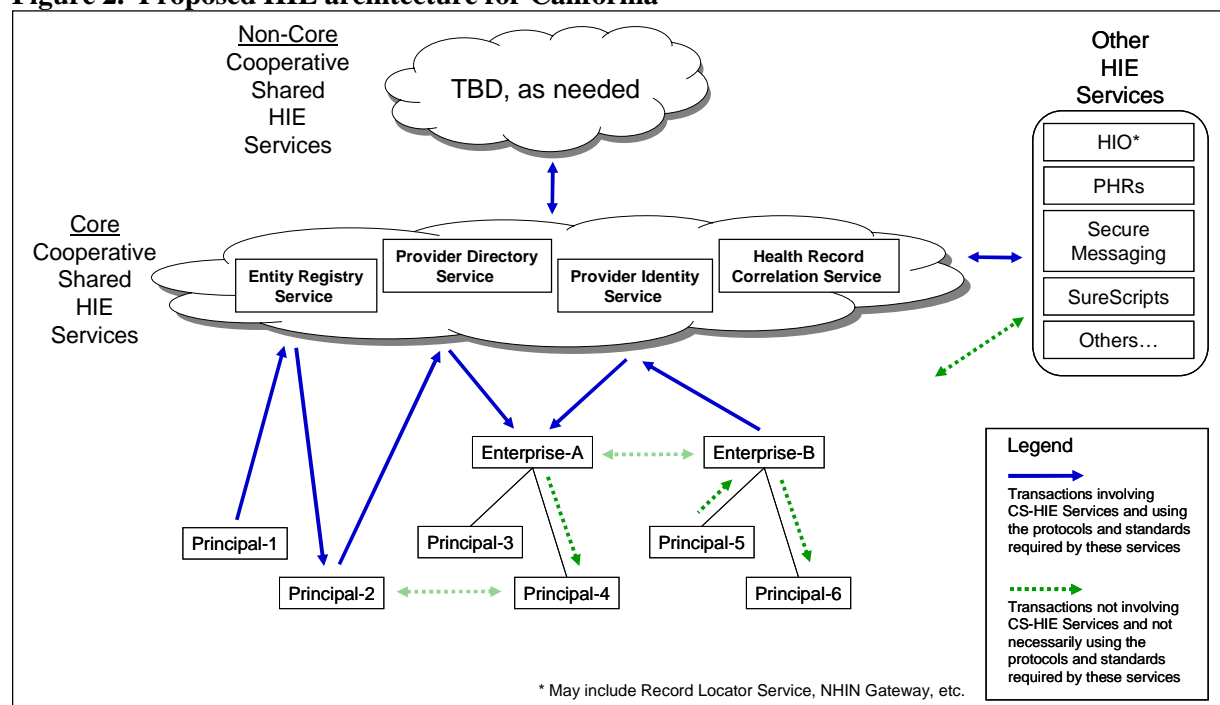
Cooperative Shared HIE Service (HIE Service): An HIE Service that (1) is available to any eligible stakeholder in the CA health care system to enable HIE, (2) is managed, overseen, regulated, and/or financially supported to some extent by the GE under the State HIE Cooperative Agreement Program, and (3) is designated as a “Cooperative Shared HIE Service” by the GE.

HIE Infrastructure: The complete set of technical resources that enable HIE, including HIE Services, other HIE Services, and the agreed-upon protocols, standards, and policies for health information exchange.

HIE Architecture: The set of HIE Services and the specified ways that eligible providers and other entities interact with these services to achieve HIE.

5.2.2 Architectural Components and their Relationships

Figure 2. Proposed HIE architecture for California



The elements of the architecture are briefly summarized below and further described in the following sections.

- Principals: The principals that engage in HIE may be part of larger enterprises (e.g., “Principal-6”) or they may be “stand-alone, i.e., their own enterprise, such as a solo practitioner or an independent pharmacy (e.g., “Principal-1”).
- Enterprises: If principals are part of larger enterprises, they may use the resources of those enterprise as HIE Services to communicate with other principals in the same enterprise, or they may use the resources of those enterprises as HIE “gateways” to communicate with principals in other enterprises (including via an HIO). For example, a hospital (“Principal-5”) in an IDN (“Enterprise-B”) could use the HIE Services of the IDN to transmit a discharge summary to a physician (“Principal-6”) in the same IDN, or it could use an HIE “gateway” provided by the IDN to locate and send the discharge summary to a physician (“Principal-4”) who is not affiliated with the IDN.
- HIOs: Enterprises may be part of a regional HIO (if one is available) or they may be “stand-alone”. If part of an HIO, enterprises may use the various resources of the HIO (such as a record locator service or a NHIN Gateway) as HIE Services to communicate with principals within the same HIO but outside of their enterprise, or they may use the resources of the HIO as a “gateway” to communicate with principals in other HIOs or in no HIO.
- E-Prescribing, PHRs, or other HIE services: There may exist HIE Services furnished by entities other than the enterprise or the HIO to which that a provider belongs. These “Other HIE Services” may include untethered PHRs, commercial prescription routing networks, or secure messaging systems. A principal may benefit from these other services by either interacting with them directly, by interacting with them via its enterprise, or by interacting with them via an HIO. For example, an HIO may provide a gateway for small physician practices to appropriately format and transmit electronic prescription to an e-prescribing network.
- Core Cooperative Shared HIE Services: In addition to the resources described above, there also exists a set of Core Cooperative Shared HIE (HIE) Services that provide a federated identity management service, directory service, and health record correlation service. These services are intended to create a broadly trusted framework for identity-management, authentication, and electronic addressing to facilitate the HIE transactions otherwise

undertaken by the principals, enterprises, HIOs, and Other HIE Services described above. Transactions that use the Core HIE Services must conform to the specific protocols and standards defined for these services (see Legend in Figure 2). For example, an independent hospital in one part of the State (“Principal-2”) may wish to send a discharge summary to a physician (“Principal-4”) that is part of a large IDN (“Enterprise-1”) in another part of the State. The hospital would look up the physician’s identity and electronic address via the Core HIE Services using the specified protocols, authenticate for purposes of the transaction using the Core HIE Services using the same protocols, and transmit the discharge summary to the physician’s IDN. Upon receipt, the IDN would look up the hospital’s electronic identity and verify its credentials using the Core HIE Services, and then deliver the document to the physician using its own internal communications protocols.

- Non-Core Cooperative Shared HIE Services: These shared services provide additional functionality to certain principals, enterprises, HIOs, and Other HIE Services for which the functionality would be otherwise unavailable. For example, the non-core HIE Services may include an NHIN gateway for principals that are not part of a large enterprise, HIO, or other entity that could otherwise provide this service.
- Bi-Lateral Communications: Note that enterprises or principals may, in certain cases, choose to have dedicated bi-lateral communication channels with other enterprises or principals that involve neither an HIO nor the HIE Services. For example, an IDN (“Enterprise-A”) may be part of an HIO, but may choose to use an existing lab-reporting interface it has developed to a national reference lab (“Enterprise-B”), rather than the lab-reporting service provided by the HIO.

The remainder of this section describes each of these components and their interactions in more and provides several HIE use cases to illustrate how the architectural components may be used to facilitate HIE.

5.2.3 Core HIE Services

The Core HIE Services are intended to create a foundation for organizations and participants to exchange health information across their organizational boundaries, such that two entities that have not necessarily exchanged information previously can find each other, positively identify each other in a manner they both trust, determine where and how to effectively exchange health information, exchange information in

a secure manner that supports both authorization decisions and the appropriate logging of transactions, and reconcile the identity of the individual patient to whom the information pertains.

The Core HIE Services consist of an *Entity Registry Service*, a *Provider Directory Service*, a *Provider Identity Service*, and a *Health Record Correlation Service*. These services provide five primary functions:

1. A **trusted process for positively identifying persons and organizations** with which one intends to exchange health information. Positive identification is provided through entries in the Entity Registry Service, a designated electronic registry of legal entities that have been certified as authentic and reputable by a trusted third party. Certified entities, in turn, provide trusted identifying information about the specific persons, departments, and other “principals” within their spheres of control with which health information may be directly exchanged.
2. A **trusted registry of health network nodes** that can send or receive HIE transactions across organizations. The identities of these network nodes are also maintained as entries in the Registry Service and are certified as authentic and reputable by a trusted third party. The entries allow the information systems that send and receive HIE transactions to verify each other’s legitimacy, to mutually authenticate each other, and to protect health information in transit from disclosure or corruption. Each registered network node in the Registry Service must be associated with a single legal entity also registered there.
3. A **trusted directory of electronic addresses** for “principals” with which health information may be exchanged (i.e., organizations, departments, applications, and/or persons). These addresses, which may be maintained within the Provider Directory Service, are specific to the various kinds of HIE transactions offered (e.g., sending lab results, requesting medication lists, etc.). Users or information systems may use these directory entries to determine the correct address for sending specific kinds of transactions intended for specific recipients.
4. A **trusted directory of the communication protocols and data standards** that may be used to exchange health information with specific principals (i.e., organizations, departments, applications, and/or persons). These directory entries, also maintained in the Provider Directory Service, inform programmers and information systems about the set of transactions that are supported by various organizations, departments, applications, and persons and the appropriate communications protocols and data standards to use for each one.

5. A means for associating health record information across separate organizations such that health information, when exchanged, may be reliably associated with the correct patient.

The goal of the Core HIE Services is provide a light-weight and relatively flexible infrastructure to provide these functions, upon which additional services and resources for health information exchange may be layered.

Illustrative “use cases” of how the *Entity Registry Service*, *Provider Directory Service*, *Provider Identity Service*, and *Health Record Correlation Service* may be leveraged to meet the HIE criteria for meaningful use are found in Appendix 10.

The following sections describe the proposed Core HIE Services in more detail.

5.2.4 Entity Registry Service

Purpose: The Entity Registry Service is intended to provide a trusted registry of the legal entities that are taking responsibility for authenticating the principals engaged in HIE transactions. It is also a trusted registry of the health network nodes that may be the senders or recipients of “transmissions” of HIE. The Service comprises part of a federated identity management system for HIE, and serves to inform parties and systems engaged in HIE transactions about the validity and authenticity of counterparties to their transactions.

The Entity Registry Service is not intended to be a registry of individual health care professionals, patients or consumers, nor to provide for the provisioning of such individuals for purposes of electronic transactions. Health care professionals (including physicians) will be provisioned and registered by their own institutions, by designated third parties (such as HIOs), or by the Provider Identity Registry. A registry of consumers/patients for purpose of identification and consent management is outside the scope of the HIE Service architecture at this time, but may be defined as part of the architecture in the future or may be provided outside of this architecture.

Description: Entries in the Entity Registry Service are essentially trusted “bindings” of legal entities (as defined by their names, locations, alternate unique identifiers such as National Provider Identifiers (NPIs), type (physician practice, lab, emergency room, etc.) to unique registry identifiers and to public encryption keys. These binding are typically represented as *digital certificates* that are signed by a trusted, centralized *Certificate Authority*. A cardinal element of the registry is that its entries are trusted as legitimate and accurate by all stakeholders in the healthcare system. This trust will require both a

rigorous process for provisioning legal entities and a timely process for modifying entries in the registry (including certificate revocation) as information about the entities changes.

Among the attributes of entities registered in the Entity Registry Service is a URL that “points” to a directory of principals at the entity who may be the recipients of HIE transactions. This URL may reference a directory service hosted by the entity itself, hosted by a trusted third party (such as an HIO), or hosted by the HIE Provider Directory Service. Regardless of which organization hosts the directory service, the service must conform to a standard interface for directory information as defined by the State HIE Cooperative Agreement Program (see Section 4.3.3)

The mechanisms by which valid entries in the Entity Registry (e.g., digital certificates) are made available may vary. The Entity Registry Service itself could have a web-services interface that allows retrieval of certificates by systems wishing to validate specific legal entities. If no entry for a legal entity were returned, the entity would be considered invalid. Alternatively, the Entity Registry Service could publish only those entries that have been revoked (i.e., a “revocation list”). If no entry for a legal entity were returned, the entity would be considered valid.

Operational Policies:

- Access to the Entity Registry Service is confined to entities that also have entries in the registry. Information in the registry, while not confidential, could be abused if available to the general public. This policy is analogous to that currently specified for NHIN Service Registry: “All Nationwide Health Information Exchange (NHIE) to Service Registry communication must be authenticated and digitally signed via [digital certificates] to ensure only authorized and properly authenticated NHIEs are allowed to communicate with the Service Registry.”¹⁷
- Write access to the registry is very rigorously controlled, and confined to certificate authorities with special authorization. The process and policies by which entities will qualify for registration will need to be established and operationalized by the GE.
- Having an entry in the Entity Registry Service and/or using the service are entirely voluntary. If entities are able to achieve the health information exchange they require in the absence of an entry in this service, they are not obligated to have one, as long they comply with State and federal privacy and security requirements. Also, entities may maintain entries in the

¹⁷ NHIE Service Registry, v1.1.

Entity Registry Service and access the entries of other entities without being obligated to use any other Cooperative Shared HIE Services (such as the Health Record Correlation Service). However, legal entities are obligated to have an entry in the Entity Registry Service if they wish to use any other Cooperative Shared HIE Services, because an entry is required for trusted authentication with respect to all Cooperative Shared HIE Services.

Technology:

Resources from the NHIN Architecture: The NHIN architecture does not include a discrete service that is identical to the Core Entity Registry Service described above. However, an analogous service exists in the form of the “NHIE¹⁸ Service Registry” specification. This specification defines the capabilities and interfaces of a registry that maintain the information required for one NHIE to discover the existence of other NHIEs within the NHIN, and the associated information that enables one NHIE to establish a connection to another NHIE. Specifically, an NHIE Service Registry is intended to contain the following information about all NHIEs within the NHIN:

- The name of the NHIE
- The unique network identifier (Home Community ID) of the NHIE
- A Uniform Resource Identifier (URI) where the public key of the NHIE x.509 security certificate can be accessed
- A URI where the Web Services Description Language (WSDL¹⁹) interface definitions for the NHIE can be accessed
- Contact information for the NHIE’s technical point of contact

With this information, one NHIE can establish a secure connection to another (using its x.509 public key), locate and invoke the services of other NHIEs (based on the endpoints defined in the WSDLs), and uniquely identify and direct messages to other NHIEs.

¹⁸ “NHIE” = NHIN-enabled HIE, i.e. an HIE that is capable of discovering information in other NHIEs and exchanging information with these NHIEs. Note that “HIE” in this context is synonymous to “HIO” as defined in this document.

¹⁹ WSDL = Web Service Definition Language, a non-proprietary standard format for specifying the services provided by a web-services node (an HIE in this case), where and how to access these services, and the data formats in which information will be passed in service requests and responses.

The selected platform for the NHIE Service Registry is based on the Universal Description Discovery Interface (UDDI) version 3.0.2 specification.

NHIE Service Registries are similar to the Core Entity Registry Service described above in that they both represent certain identifying attributes of data trading partners and they both provide a means for accessing the public keys of trading partners for purposes of authentication.

However, there are also several differences between the Service Registry specified for the NHIN architecture and the Core Registry Service described above:

1. The NHIE Service Registry is intended to store information about HIEs (or HIOs, as referred to in this document). The Core Entity Registry Service is intended to store information about the various kinds of legal entities that may engage in HIE, such as physician practices hospitals, immunization registries, etc. Registered legal entities may participate in HIOs, but they are more granular organizations than HIOs themselves. It is possible that the specifications of the NHIE Service Registry could be repurposed for this different task by expanding the concept of “services” to include the individual legal entities that participate in HIE transactions.
2. The NHIE Service Registry provides the address of a WSDL specification for the HIO, which describes the services that an HIO supports and where and how to access those services. The Core Registry Service does not reference such a WSDL. Instead, comparable information is represented in separate directory services that are hosted by the registered entity or by the Core Provider Directory Service, as described below. The Core Registry Service and *Core Provider Directory Service* could be consolidated into a single service, to more closely approximate an NHIE Service Registry. However, because only a subset of entities will choose to publish their providers’ addressing information in the HIE Provider Directory Service, it may make more sense to keep the Entity Registry Service and Provider Directory Service separate.

5.2.5 Provider Directory Service

Purpose: The Provider Directory Service is intended to provide default information about where to direct transactions intended for specific principals to HIE transactions and how to formulate the transactions such that they can be correctly processed when received. Note that “provider” in this context denotes any principal to an HIE transaction, and is not confined to health care providers. Hence, entries may exist in the Provider Directory Service for physician practices, hospitals, hospital departments, laboratories,

pharmacies, personal health records, immunization registries, payers, and any other entities to whom health information could be legitimately sent or from whom health information could be requested. Each principal, however, must be associated with a legal entity registered in the Entity Registry Service.

The Provider Directory Service allows registered legal entities to publish the address(es) at which their providers accept specific HIE transactions and the communication protocol(s) they support for these transaction. This information is available to any authorized counterparties who wish to conduct such transactions on an ad hoc basis, but would otherwise lack the addressing and protocol information to do so . For example, if a physician wishes to send a patient’s key clinical information to a colleague at another organization, the Entity Registry Service would allow him to look up the electronic identity of the organization and the Provider Directory Service (if used by that entity) would inform his EHR as to the network address to which the transaction should be addressed and the communication protocol(s) with which the transaction should be conducted (including protocols for transport, security, and data representation).

Entities may publish a registry of their providers in any manner that conforms to the standards of the State HIE Cooperative Agreement Program, and need not use the HIE Provider Directory Service. This service is provided as a Core HIE Service for those entities that cannot or choose not to host their provider directory themselves (e.g., small practices).

The Provider Directory Service does not perform any of the network routing required to conduct HIE transactions – it only provides the network address to which the transaction should be directed (see below). Network routing is expected to be performed by other means, including the existing public internet routing infrastructure as well as the existing infrastructure of enterprises, HIOs, and other HIE services.

Description: The Directory Service will provide a database of directory entries that provide the following mappings:

Entity + Principal + Transaction Type => Network Address + Protocol

Where

“Entity” is the identifier of an entry in the Entity Registry Service. This will be a key attribute that supports lookups by specific entity.

“Principal” is the identifier of a principal within the designated entity. Directory entries will include certain minimum attributes of these principals, such as name, mail and telephone contact information, secondary identifiers, professional role (if a person), etc. These attributes support discovery of principals, and they will likely vary depending on the type of principal.

“Transaction Type” is an element from a pre-defined set of transaction types. This set may include transactions such as “Submit New Medication Prescription”, “Submit Laboratory Order”, “Send Laboratory Result”, “Send Encounter Summary”, “Request Patient Summary”, “Request Insurance Eligibility Information”, etc. The set will be specified in the course of defining the Core HIE Services.

“Network Address” is a Uniform Resource Locator (URL), such as <https://clinic.newport.com/inbox/DischargeSummary>.

“Protocol” is a designation of the protocol “suite” that can be processed for the indicated transaction at the indicated network address. The protocol suite, in turn, designates the combination of transport, security, and data-representation protocols that are recognized at the specified network address. For example, a protocol suite might designate Simple Object Access Protocol (SOAP) v1.1 over HTTP for transport, TLS, 2-factor authentication, and the Security Assertion Markup Language (SAML) Token Profile v1.1 for user authentication, and the HL7 CCD for data representation. Multiple entries for a single combination of Entity, Principal, and Transaction Type could specify alternative addresses and/or protocol suites that may be used for a transaction.

Operational Policies:

- For principals that are part of a larger enterprise or participate in an HIO, the network address in some or all of their directory entries may be that of their enterprise or HIO. The enterprise or HIO is then responsible for routing the transaction to the intended providers²⁰ (for example, see “Enterprise-A” and “Principal-4” in Figure 2). This enables large enterprises and HIOs to manage the routing of traffic within their spheres to reach the final recipient, rather than having to maintain entries in the HIE Provider Directory Service for all of the physicians, departments, and applications that they represent.
- Information in the Provider Directory Service must be secure because it represents a trusted “binding” between a principal and the address to which transactions intended for that

²⁰ Note that delivery, in this case, will require that the identity of the intended recipient (principal) is included with the transmitted message.

principal are directed. Hence, access control for modifying directory entries needs to be rigorous. If the addressing information were compromised, for example, a physician might send a message intended for another physician to an unintended and unauthorized third party. Also, read-access to the Directory Service should require authentication via a legal entities Entity Registry Service entry, so that entities will feel confident publishing their provider directory information in the Directory Service without undue risk of spoofing, denial of service attacks, and other malicious behavior.

- If a principal has an entry in the Provider Directory Service for a specific transaction type, then the principal must have at least one entry for the transaction type that conforms to a designated set of communication protocols conformant with the Cooperative Shared HIE Services standards (see Section 4.3.3.2). In other words, principals must support at least the designated standard communication protocol for all transaction types that they publish in the Provider Directory Service. At the same time, providers (and their entities) may support other, non-standard communication protocols for the same transaction types. Note: The same policy applies when legal entities host their own provider directories, rather than using the HIE Provider Directory Service.

The rationale for this policy is so that counterparties can count on principals supporting at least the designated standard communication protocol for the transactions they “publish” via the Provider Directory Service. Counterparties are not obligated to use the designated standard communication protocols, but principals are required to offer it if they offer any protocols for that transaction.

Having entries in the Provider Directory Service or using information from the Service for HIE transactions is entirely voluntary. Entities may choose to host their own provider directories or use the hosting services of a third party for their provider directories. Organizations may choose to acquire information about the network addresses and communication protocols that counterparties support for various transaction types in any manner they wish, including via direct agreements with their data trading partners or via referencing a separate third-party resources (such as an HIO). Even if providers publish directory entries for certain transaction types in the Provider Directory Service, they may accept instances of those transactions at different network addresses and/or via different communication protocols than those designated in the published entries. Last, providers need not publish in the Provider Directory Service all the addresses and/or communication protocols at which they will process transactions, but they must support the addresses and communication protocols that they do publish.

Technology

Resources from the NHIN Architecture: The NHIE Service Registry specification (referenced in Section 4.3.1.1) specifies that the registry be represented as a UDDI service catalog and that entries in the registry be represented per the UDDI data model. The data model for each entry consists of the following XML objects:

- BusinessEntity* – Information about the business or organization providing the services; each BusinessEntity may contain 0 to many instances of a BusinessService
- BusinessService* – Descriptive information about each of the services that the business entity provides; each BusinessService may contain 0 to many instances of a BindingTemplate
- BindingTemplate* – Technical information about the service entry point and implementation specifications for a service; each BindingTemplate may reference 0 to many instances of a tModel
- tModel* – The detailed technical specifications of the service interface, such as details of the SOAP protocol used, security specifications, data representations, etc.

These objects are analogous to the components of Directory Service entries, as specified above. In particular, the following correspondences exist:

BusinessEntity => Entity + Principal

BusinessService => Transaction

BindingTemplate => Network Address

tModel => Protocol Suite

If the Entity Registry Service and Provider Directory Service were combined into a single service, the UDDI model and the interface specifications of the NHIE Service Registry may be appropriate for representing the directory entries as specified above. Further evaluation of the UDDI data model, the NHIE Service Registry specification, and the requirements of the Entity Registry Service and Provider Directory Service as described above is required. If the NHIN specifications do not prove suitable for the functionality needed in the Directory Service, a different technical model may be required for this service.

5.2.6 Provider Identity Service

Purpose: The Provider Identity Service is intended to provide a widely trusted mechanism for provisioning and authenticating providers involved in HIE transactions (again, “providers” in this context refer to principals as defined in Appendix 10, i.e., individual health care providers, health care administrative staff, or health I.T. applications that engage in HIE transactions). Although many legal entities may be trusted by their counterparties to provision and authenticate principals themselves, other entities (particularly smaller ones) may not be trusted by their counterparties and may require a trusted “third party” identity service. The Core HIE Provider Identity Service is intended to fill this role.

Description: The service will be responsible for (1) maintaining the required information to authenticate principals registered with the service, (2) reliably performing the authentication step, (3) generating the necessary token(s) to assert a successful authentication, and (4) making these tokens available in a secure manner to the authenticated principals and/or the principals’ counter-parties in transactions.

These authentication assertions will include the principal’s key information from the Provider Identity Service, including unique identifier, identifying attributes, and public key. The assertions will also contain information about the authentication event, including the authentication method (password, two-factor, etc.). The assertion will serve as a trusted “binding” between a person or application that is seeking access to health information and the identity of a principal as maintained in the Provider Identity Service.

Authentication assertions generated by the Provider Identity Service may be used to authenticate end users for “front channel” HIE transactions (such as web-browser-based interactions with an immunization registry) or they may be used to authenticate enterprises or information systems for “back channel” transactions (such as the transmission of a clinical summary from one EHR to another).

The Provider Identity Service may support multiple methods of authentication, including weak methods (password only) and strong methods (two-factor authentication involving software tokens, physical tokens, and/or biometrics). The Authentication Service, itself, will not require any specific level or technique of authentication for any specific transaction type. It will be up to the access-control policies of data-trading partners to accept or reject the authentication method used for a requested transaction. Note that transactions may also contain separate *authorization assertions* that indicate the role of the principal seeking access with respect to the patient and the reason for the requested access (see “Authorization” in Section 4.3.1.4).

Operational Policies

- Write access to the Provider Identity Service is very rigorously controlled. Specifically, only organizations (*certificate authorities*) that are certified by the GE to provision and credential providers will be entitled to update the information in the Provider Identity Service.
- To ensure the maximum degree of trust, management and operations of the Provider Identity Service will be assigned by the GE to a specially designated and certified organization. The organization(s) will be entrusted with, responsible for, and certified to perform the provisioning, credentialing, and authentication of principals in a secure and rigorous manner. The organization(s) may be non-profit, for-profit, or government entities.
- Authenticating via the Provider Identity Service for purposes of HIE is entirely voluntary. Authentication for HIE transactions may be performed directly by the entities involved in the transactions, if both parties to the transactions honor that method of authentication.

Technology

Resources from NHIN Architecture: The NHIN architecture does not include services or specifications for performing authentication, per se. It does, however, include in its Messaging Platform Specifications the SAML Token Profile v1.1 (based on SAML v2.0). This profile may be used to standardize the representation of the authentication assertions generated by the Provider Identity Service and accepted by counterparties to HIE transactions.

5.2.7 Health Record Correlation Service

This service will assist the recipients of exchanged health information (including intermediaries, such as HIOs) to associate the information with the correct patient health record. The service will help in the reconciliation of identifying attributes of patients, such as name, date of birth (DOB), local medical record number, or health plan identifier when they vary across health record systems. The specific operations that the service will provide and the mechanisms it will use have not yet been defined; importantly, the TAC and TWG acknowledge the need for a process to ensure the integrity and accuracy of this service by means including but not limited to patient input.

5.2.8 Support for Other Core Functions

Authorization: The proposed HIE services currently includes no service for performing or facilitating the authorization of HIE transactions. This is for two reasons. First, it is assumed that many counterparties

to HIE transactions will trust no other entity to make access-control decisions. Organizations are typically conservative with respect to the electronic disclosure of personal health information and even the acceptance of health information from other enterprises. Secondly, any centralized patient-consent database would require a registry of patient identities, which may not be politically feasible in the near term.

However, the TAC and TWG proposes to support authorization decisions by specifying use of standard SAML attribute assertions within transactions that use the HIE Services, as well as use of the standardized codes for “user role” and “purpose for use” as specified in the NHIN Authorization Framework.²¹ This level of standardization will enable entities to better make access-control decisions when the only information they have about the counterparty to an HIE transaction is derived from the Entity Registry Service and the transaction itself.

Logging: This has been suggested as an additional Core HIE Service. In this architecture, however, logging of all interactions with the Core HIE Services (e.g., registry lookup, directory update, provider authentication) will be performed by logging modules of these services themselves, rather than by a separate “Logging” service. This will likely be easier to implement than a separate logging service, but may make it more difficult to provide auditing of such interactions as a core service in the near term. It is not yet clear how important it will be to provide an auditing service for interactions with the core HIE Services.

Logging of actual HIE transactions enabled by the Core HIE Services, including lab result delivery, request for key patient information, and eligibility check, will be performed by the service end points involved in HIE transactions, rather than by any component of the Core HIE infrastructure.

Protocol Translation: This has been suggested as an additional Core HIE Service. It remains to be determined whether it is feasible for protocol translation to occur centrally, or whether the sending and receiving systems should perform protocol translation before sending and/or after receiving transactions.

5.2.9 Non-Core HIE Services

In addition to the core services described above, enabling health information exchange needed to achieve meaningful use for all eligible providers in California may require additional services to be provided under the State HIE Cooperative Agreement Program. These services would provide specific functions needed for HIE that are not otherwise available to eligible providers and/or to the counterparties with

²¹ NHIN Authorization Framework Service Interface Specification v2.2.

whom they need to exchange health information. These services would be layered on top of the Core HIE Services on an as-needed basis over time.

Although no specific non-core Cooperative Shared HIE Services are planned at this point, potential services that may be needed in the future include:

- An NHIN gateway for provider organizations that are not part of enterprises, HIOs, or other provider aggregations that have their own NHIN gateways.
- A trusted consumer registry (or registries) that may be used as the basis for federated identity management, authentication, and authorization involving consumer identities and their attributes.
- An administrative portal and/or EDI routing service that enables eligible providers to conduct eligibility-checking of claims submission electronically across payers for which those services are currently unavailable, pending revision of the CalPSAB guidelines, which currently disallow this type of exchange under privacy rules regarding opt-in requirements. CalPSAB reports that these rules are under revision, so in the event this service becomes possible, it will be built in compliance.

As envisioned for the HIE architecture, non-core HIE Services would be accessible to any principal, enterprise, or existing HIE service that could benefit from them. However, their use would be entirely optional, even for entities that otherwise use the core HIE Services for authentication and other functions. For example, an HIO that did not have its own NHIN gateway could route NHIN transactions through the HIE gateway, whereas another HIO could operate its own NHIN gateway and only use the core HIE services to authenticate users of that gateway.

Use of non-core HIE services, however, would require at least an entry in the Entity Registry Service of the core HIE layer.

5.2.10 Protocol Standards for Cooperative Shared HIE Services

The core and non-core HIE services will be based on and accessible through a set of specific standards for HIE transactions. The specification of a small set of standards is necessary to enable the HIE Services to support HIE across principals and enterprises whose information systems today use a large variety of mechanisms for transport, security, and data representation. Principals and enterprises in California are

not required to use the standards below for all of their HIE transactions, only those involving the core and non-core HIE Services.

5.2.11 Standards for Core HIE Services

Entities wishing to use the Core HIE Services must interact with these services using the transport and security standards specified below.

- Transport Standards
 - SOAP v1.2 and RESTful communications protocols as specified in the NPRM.
- Security Standards taken from the NHIN specifications
 - SAML Token Profile v1.1 for authentication assertions
 - SAML Token Profile v1.1 for attribute assertions
 - SNOMED-CT Code Sets for “User Role” and NHIN Code set for “Purpose for User”.
This is the coding system that will be required by 2013. It is the ICD-10 CM and PCS (Procedural Classification System) – coding used for procedures and surgeries for clinical and billing use. Note, SNOMED is not currently in use now.

SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms), is a systematically organized computer processable collection of medical terminology covering most areas of clinical information such as diseases, findings, procedures, microorganisms, pharmaceuticals etc. It allows a consistent way to index, store, retrieve, and aggregate clinical data across specialties and sites of care. It also helps organizing the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research International Classification of Diseases (ICD 10) and Procedure Classification System (PCS) should also be included here

- X.509 Token Profile v1.0 for digital certificates
- TLS v1.0 for transport-level authentication and encryption
- UDDI v.3.0.2 for Registry Service and Directory Service, pending evaluation.

5.2.12 Standards for Other HIE Services

When using non-core HIE Services for HIE transactions, entities must interact with these services using the standards below, based on the transaction type. Also, as specified in the operational policies of Section 5.2.4, the transport, security, and information-payload standards specified below must be *offered* for every transaction that a principal publishes in the Provider Directory Service, or in an alternative directory service hosted elsewhere.

The reason for this requirement is to specify a well-defined “service bus” for transactions that use HIE services, so that these services can be implemented and supported efficiently and need not support the many transport, security, and data standards that are in current use for HIE across the California health care system. The specification does not, however, obligate the participants in HIE transactions to use these standards if they use no Core or Non-Core HIE services for HIE. For example, if a reference laboratory and EHR already used a non-standard format for exchanging lab results, they could continue to do so. However, if users of the EHR published one or more entries in the Provider Directory Service for receiving lab results, at least one of the entries would need to specify the standard protocol for those transactions. The proposed standard protocols are:

- The transport and security standards specified above for the Core HIE Services, plus:
- Health information payload standards, by transaction type
 - Transmit Electronic Prescription => SCRIPT 8.1, with any medication terminology that’s mapped to RxNorm in UMLS
 - Transmit Electronic Lab Result to EHR => HL7 v2.5.1? ELINCS? HITSP C36? [no standards were specified in CMS IFR]
 - Check Insurance Eligibility => ANSI X12 270/271 compliant with CAQH CORE Rules, Phase 1
 - Submit Insurance Claim => ANSI X12 837 compliant with CAQH CORE Rules, Phase 1
 - Provide Patients with Health Information => HL7 CCD Level 2, based on HL7 CDA R2 *or* ASTM E2369 CCR
 - Provide Summary-of-Care Record => HL7 CCD Level 2, based on HL7 CDA R2 *or* ASTM E2369 CCR

- Submit to Immunization Registry => HL7 2.3.1 or HL7 2.5.1, HL7 CVX Code Set

{Need to check with CA-SIIS to see if they are embracing one version over the other. 2.3.1 is what is more commonly deployed but many CA regional registries don't even support that.}

- Submit Lab Result to Public Health => HL7 v2.5.1 LOINC codes must be used.
- Submit Syndromic Data to Public Health => HL7 v2.3.1 or HL7 v2.5.1

5.2.13 Integration of the HIE resources/services from various sectors

Please refer to Figure 2 in Section 4.3 for a graphical representation of the relationships described below.

5.2.13.1 From Governance Entity (i.e., the HIE Services)

Integration of Core and Non-Core HIE Services. Non-Core HIE Services will use elements of the Core services to the extent needed. At a minimum, non-core services will leverage the Entity Registry Service to authenticate the legal entities and the principals that wish to access non-core services. For example, one potential non-core service is a centralized gateway for accessing insurance eligibility information across multiple payers (see Section 4.3.2). Access to the gateway may only be granted for requests originating from health network nodes registered in the Entity Registry Service and made by users and applications authenticated by legal entities registered in the Entity Registry Service. If needed, the gateway could also leverage the capabilities of the Health Record Correlation Service to associate eligibility inquiries with the appropriate member-identifying information at various health plans.

5.2.13.2 From Private Sector

Regional HIOs: RHIOs may use certain of the Core HIE Services to facilitate various HIE services they provide to local stakeholders. For example, a RHIO that provides a service for standardizing the format of lab results and routing results to the appropriate recipients could leverage the Provider Directory Service to store the addresses and supported reporting formats for various labs and physician practices within its region. The RHIO could also leverage the Entity Registry Service to authenticate legal entities from outside its region that send lab results to providers within the region, thereby providing a “gateway” for other RHIOs to send lab results to local providers. As another example, a RHIO may leverage the Health Record Correlation Service to help match data coming from outside the local area to health records maintained within the area, which may contain somewhat different identifying attributes for the same patients.

One example is how an e-prescribing network can leverage the Entity Registry Service to streamline its own processes for provisioning and authenticating the physician practices in their network. A physician practice that has an existing Entity Registry Service entry but is not yet part of the e-prescribing network could begin using the network more quickly if its entry in the Entity Registry Service were honored by the network. Similarly, the e-prescribing network could leverage the contents of the Provider Directory Service to correctly route renewal requests to ordering providers or new prescriptions to pharmacies that may currently be outside its network.

5.2.13.3 From State and Local Governments

With respect to the architecture depicted in Figure 1, the administrative systems and clinical data registries operated by State and local governments comprise *Enterprises* that need to exchange information with each other and with enterprises in the private sector for purposes of collecting or disseminating patient-specific health information. Examples of such enterprises include the Department of Health Care Services (and its MMIS systems) and the State and local departments of public health (and their various registries). Several examples are provided below.

Medicaid Management Information System (MMIS): The MMIS may interact with the HIE Services in at least two ways:

1. MMIS may leverage the Entity Registry Service and (possibly) Provider Identity Service to authenticate and authorize requests from providers for administrative information, such as eligibility and benefits information for Medi-Cal beneficiaries. In this mode, requests to MMIS would include authentication and authorization assertions signed by legal entities registered in the Entity Registry Service. If the MMIS trusted the legal entities thus registered, this trust would obviate the need for MMIS to maintain its own registry of providers authorized to access to MMIS (include their passwords, etc.) and to perform the authentication itself. These functions could be delegated to the trusted legal entities.
2. MMIS may leverage the Entity Registry Service, Provider Directory Service, and Health Record Correlation Service to make requests to providers for access to clinical information, such as medication lists or lab results for Medi-Cal beneficiaries. In this mode, MMIS would, itself, be a registered legal entity in the Entity Registry Service. An MMIS user would locate the provider of interest in the Provider Directory Service and submit a request to retrieve clinical information for a specific Medi-Cal beneficiary (identified by name, DOB, and Client ID, for example). The contacted provider would authenticate the request using

MMIS's entry in the Entity Registry Service and would use the Health Record Correlation Service to match the request to the correct patient in its EHR. The information would be sent back over a secure channel, because both the MMIS system and the provider's EHR were health network nodes also registered in the Entity Registry Service.

Immunization Registries: Immunization registries could use the Core HIE Services when authenticating requests from providers to submit or retrieve immunization records. This process would be very similar to case #1 described above for MMIS. The immunization registry would leverage the trust infrastructure established by the Entity Registry Service to obviate the need to maintain its own registry of users (for a more detailed description of this process, see Section 4.6).

Public Health Databases: Public health databases used to monitor reportable diseases could also use the Core HIE services when authenticating requests from providers to submit data (including lab results and syndromic findings) and from public health agencies to access the data.

Quality Reporting Programs: California's Office of Statewide Health Planning and Development (OSHPD) collect over 16 million patient records annually from hospitals and licensed ambulatory surgery clinics. The data are used by OSHPD to measure quality of care as well as service utilization and cost and are provided to researchers under strict control. Facilities report these data by uploading files via an internet web page. Data are then subject to editing and correction. These data reporting activities could potentially use Core CS-HIE Services to transmit data. As noted in section 1.3.2.5 above, the capacity to have this reporting accomplished automatically will result in decreased workload for providers and allow OSHPD and other public health agencies to shift from the business of collecting data to analyzing data and providing aggregate results back to providers and others in a timely fashion.

5.2.14 Alignment with NHIN and NHIN Direct

HIE will connect with the NHIN according to specifications determined by the NHIN workgroup and conform to the standards already specified by the NHIN, such as IHE and HL7. In March, it was announced that NIEM, a partnership of Justice and the DHS, will be a new framework for developing information exchange standards which describe content and processes among organizations that share data as part of their daily business operations. HIE will adapt specifications to conform to the new NIEM framework as it is defined over time.

In March, the NHIN workgroup announced the launch of NHIN Direct, a new service that will use "lightweight" versions of NHIN's current standards and services to allow for the transfer of electronic

data without a high degree of technical adaptation and overhead costs. Functions offered to providers using NHIN Direct include:

- Establishing summaries of care records and transition of care referrals;
- Exchanging test results with clinical laboratories; and
- Reconciling medication.

The system also will supply foundation services and standards to support patient engagement and public health. HIE will be designed to interoperate with NHIN Direct to expand participation in the overall NHIN by participants in California.

5.3 Necessary Policy Support and Participation Rules

The following policies are proposed for potential users of HIE Services:

- “Net Neutrality” => if an entity publishes a provider directory (either itself or via the Provider Directory Service) for a specific type of transaction, the entity must support transactions of that type originating from any other entity that has valid access to the provider directory (subject to the authentication and access-control policies of the principals). The network infrastructures of principals may not limit access or give preferential treatment to traffic based on the source of the traffic.
- Minimum Participation => Every entity that wishes to use the HIE services for any purpose must have (at a minimum) a validated entry in the Entity Registry Service and must publish a provider directory that is compliant with the standards of the State HIE Cooperative Agreement Program.
- Optionality => the use of HIE Services (core or otherwise) is entirely optional for any entity, enterprise, or other HIE service.
- Transaction Independence => An entity, enterprise, or HIE service may use the HIE Services (core or otherwise) for any supported transaction without being obligated to use HIE Services for any other transaction (with the exception of having an entry in the core Entity Registry Service, which is required to for an entity to access any of the HIE Services)

5.3.1 The role of DURSA(s)

The Data Use and Reciprocal Support Agreement (DURSA) is a comprehensive, multi-party trust agreement that will be signed by all NHIEs both public and private, wishing to participate in the NHIN. The DURSA provides the legal framework governing participation in the NHIN by requiring the signatories to abide by a common set of terms and conditions. These common terms and conditions support the secure, interoperable exchange of health data between and among numerous NHIEs across the country.

The DURSA is being developed as a vehicle for creating trust relationships among the NHIEs participating in the NHIN. It memorializes the expectations for NHIEs in a “network of networks” with respect to the behavior and activities of other NHIEs. Since it is a multi-party agreement, it avoids the need for each NHIE to enter into “point-to-point” agreements with each other NHIE, which becomes exceedingly difficult, costly and inefficient as the number of NHIEs increases.²²

The DURSA is a voluntary model document which is likely not intended to override California’s existing privacy rules, or rules a State may develop in its judgment to protect privacy during exchange of information. The GE and CalPSAB are responsible for determining the utility of the DURSA for California HIE.

²² Draft Data Use and Reciprocal Support Agreement developed by the NHIN Cooperative DURSA Workgroup, January 23, 2009, http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_849891_0_0_18/DRAFT%20NHIN%20Trial%20Implementations%20Production%20DURSA-3.pdf.

6. Business and Technical Operations

6.1 State-Level Shared Services

The TWG and TAC identifies priority services and advises the GE on recommendations for how services should be developed and made operational. The GE will have the authority to decide how services are developed and authority over the procurement process. As the first step in the procurement process, the GE will discuss developing the services using existing resources at the state level or the State procuring the services from an existing or new vendor.

As an example of this coordinated process, the TAC identifies a list of business requirements to the TWG. These requirements are developed in the workgroup using a matrix tool²³ which allows the group members to expand on the requirements needed for three prioritized core services: lab data exchange, eligibility processing, and clinical summaries of care encounters. After ratification by the group, the requirements are sent to the TWG for revision and approval, and then sent to the GE for procurement.

These technical services may be developed over time and according to standards and certification criteria adopted by HHS in effort to develop capacity for nationwide HIE.

6.1.1 State Managed and Supported Services/Security Issues

Please see section 4.2.3. for a description of State-managed services in California and a discussion of security issues.

6.1.2 Governance Entity Managed and Supported Data and Services

The GE will address the most following immediate needs in the near term: selecting a Board of Directors and appointing the management team, defining an approach, principles, and goals for an open procurement process, and determining policies and procedures for day to day operations.

In the mid-term time frame (defined as the procurement and operations phase, roughly the first year of HIE deployment) the GE will address selection and build of specific data and services. Based on recommendations from the TWG, the GE will identify services needed for supporting HIE services. The GE will determine the requirements for the procurement process, selection criteria, and policies and procedures including remediation for contract violations or unmet milestones.

²³ See Appendix 9. 9 for the Business Requirements Matrix.

In the long-term (defined as over the development and implementation of the HIE services), the GE will manage compliance with contractual obligations, perform evaluation functions in partnership with the selected Evaluator, and manage remediation for unmet milestones or contractual violations.

The GE will step through the following process:

1. **Identify needs** for services and specific characteristics and features to ensure successful implementation, harmonization with stakeholder needs, and fit with other services and infrastructure of the HIE services;
2. **Determine operational requirements.**
3. Initiate and **manage a procurement process** through selection of final service provider.
4. After services are procured, **manage compliance with contractual obligations** and ensure adherence to all State policies, including privacy and security guidance issues by other State entities.

6.1.3 State Management Information System (MMIS) (Medi-Cal EHR Incentive Program)

The State will continue to manage information systems related to Medicaid Management Information System (MMIS) and public health programs, and will coordinate requisite interfaces with the HIE.

6.2 Standard Operating Procedures for HIE

The GE will develop standard operating procedures (SOPs) for its core services. These SOPs will be referenced in all contractual and participatory agreements between the GE and participants in HIE.

6.3 Continuous Improvement

The GE (and in the interim period before selection, the Operations Team) will provide continuous monitoring of activities, and resolution of issues. The GE will provide a feedback loop for interests and concerns of stakeholders, and is responsible for making necessary changes and revisions to the Standard Operating Procedures as necessary.

7. Patient and Consumer Engagement with HIE

7.1 Engaging Patients, Their Families, Consumers of Healthcare, and Other Stakeholders in HIE

Throughout the Operational planning process, stakeholders addressed the need for defined approaches to the individual participants in HIE in addition to a design and implementation plans for the technical, business, and financial infrastructure. The primary groups charged with developing the approach to individual participants in HIE were the Patient Engagement Workgroup and the Vulnerable and Underserved Workgroup, both open to the public. The workgroups were convened weekly by the Workgroup tri-chairs during the operational planning process, drafted and provided content to this Operational Plan, and reviewed and commented on the Plan as a whole.

The Vulnerable and Underserved workgroup focused on the needs of both specific populations of patients and their families and as well as the issues and concerns of medical providers, health professionals, clinics, State agencies, and public programs that provide their care. These needs, issues, and concerns should be considered as the business drivers or rules that will shape the privacy and security controls inherent to HIE services. Meanwhile, the Patient Engagement workgroup focused on principles and strategies for engaging patients, families, and those involved in their care, collectively the “consumers” of health services, in health information exchange. Together, the workgroups presented a comprehensive picture of how State HIE services can serve the needs of all California individual HIE participants, both recipients and providers of services, working together to improve health for all California residents.

Extensive deliberations the Patient Engagement Workgroup revealed a need to clarify the workgroup’s understanding of the terms “patients and families” and “consumers.” This need reflects agreement that the terms are not, and should not be considered, synonymous. Knowing that terms used in HIE and HIT are evolving along with discussion of policy, the Patient Engagement Workgroup agreed to the following definitions for purposes of operational planning for HIE:

- “Consumer”: the universe of patients or potential patients; any individual who has consumed a health product or service or is likely to require attention from health service providers at some point in his or her life span.
- “Health Consumer”: an individual who self-selects for interest in health-related information, for participation in health-related groups or electronic conversations, for accessibility to marketing of health-related products.

- “Patient”: any consumer known to health service providers because care has been provided or planned.
- “Family”: persons designated by a consumer as their personal representative to be entitled to access the consumer’s electronic records through HIE. In the case of a minor, persons deemed by the State to be responsible for that individual.

This usage distinguishes those known to the health service delivery system from those not yet known (except perhaps to payers who insure them). Those not yet known may not consider themselves “patients” but are definitely “consumers.”

7.1.1 Patient Engagement Principles, Strategies, and Tactics

The Patient Engagement workgroup framed the work of developing an approach to engaging with consumers by ratifying the principles as laid out in the workgroup’s charter (see Appendix 3.) The workgroup found it important to separate the following:

- Principles of the approach, or “why” engaging with consumers is critical to meaningful HIE services;
- Strategies to effectively engage with consumers, which are the “what” of the approach; and
- Tactics, which describe “how” these strategies will be deployed.

The mapping of these principles, strategies, and tactics follows. The Patient Engagement workgroup acknowledges that not all of these tactics will be made material in the first iteration of the HIE deployment, but provides this mapping as a set of guiding principles and innovations to the GE to guide the evolution of the HIE over time in a consumer-focused manner.

Principles	Strategies	Tactics
1. Earn the trust of the health information exchange users	<ul style="list-style-type: none"> • Empower consumers to make decisions about how, when, and with whom their personal health information is shared (or not shared.) • Empower consumers with a transparent view and clear understanding of all elements of personal health information available upon 	<ul style="list-style-type: none"> • “Leavitt label”: an easy-to-read, standard notice about how patients’ personal health information is protected. • Provide Opt-in designation that is informative and easy to understand, with a defined process for non-participating consumers. • Ensure that no data from the HIE will be used or sold to third party vendors, in identifiable or de-identifiable State, without explicit consent

Principles	Strategies	Tactics
	request.	<p>of the consumer.</p> <ul style="list-style-type: none"> • Consumer to define and specifically authorize providers, provider networks, and vendors to access and share data on a specific data type, data element, or transaction. • Upon request, provide timely reports to the consumers of all accesses to the data. • Receive notification of access upon request and notification of data breach or compromise. • Upon request, receive notification of updates to personal or family data and receive notification of updates. • Provide immediate, online portal access to all data available via the HIE to the consumer, with intuitive site navigation. • Enable consumers to upload their own personal health activities and events into the HIE for exchange with their providers, making the HIE a platform for two-way exchange and not solely dependent on providers, but available to them at consumer request.
2. Fully engage patients in HIE services.	<ul style="list-style-type: none"> • Raise awareness of HIE services and their benefit. • Use varied opportunities to connect with the consumer, beyond traditional health care settings or office encounters. • Create opportunities for consumer representation throughout the State. 	<ul style="list-style-type: none"> • Establish brand for HIE that is expressed throughout the State in consumer-friendly communications. • Develop consumer education materials that are available online or in printed form to that education is not dependent on internet access. • Leverage broadest channels for consumer adoption, including segmentation of population for different messaging, if needed. • Provide education and outreach in community centers; community service centers with computer access for participants. • Establish Consumer Advisory Council to reach out to consumers, give consumers a voice, and gather input. • Conduct population testing and validation with HIE implementation efforts for base and

Principles	Strategies	Tactics
		<p>extended services that are offered, including in usability, prototyping, pilot, and quality assurance efforts.</p> <ul style="list-style-type: none"> • Establish and measure consumer use of the HIE, creating targets for engagement. • Enable patients to add their own information to health care records, adding more observations about actions performed on their own behalf, for example taking medications prescribed to them by a provider. Enable this information to be exchanged in clinically acceptable ways, when appropriate (e.g. history of medications.)
3. Establish how PHRs and other tools factor into health management and advocate the best way to use these tools to advance consumer empowerment.	<ul style="list-style-type: none"> • Each consumer should be able to choose products and services that best fit their health needs, technical capacity, and cultural preferences. 	<ul style="list-style-type: none"> • Develop consumer education materials that are available online or in printed form to that education is not dependent on internet access. • Leverage broadest channels for consumer adoption, including segmentation of population for different messaging, if needed. • Enable patient and provider to choose preferred communication channel for specific communications such as appointment reminders, including text messaging.
4. Support innovation, leveraging the HIE infrastructure.	<ul style="list-style-type: none"> • Engage innovators to develop HIE services and tools used to empower consumers. 	<ul style="list-style-type: none"> • Establish a common data framework and standards that vendors can leverage to meet the needs of the consumers in the HIE.

7.1.2 Objectives and Strategies of the Communications Plan

A subcommittee of the Patient Engagement workgroup, the Communications subcommittee, contributed a communication plan for this Operational Plan. The communication plan, which details objectives for communicating with consumers about HIE, is intended to create a framework that will include recommended staffing and funding for the plan.

The Communications subcommittee outlined the following objectives for the communications plan that are tied directly to the meaningful use criteria for Patient Engagement:

- Raise consumer and family awareness and to educate and gain their trust in HIE services and motivate use of online tools.

- Engage consumers by making HIE relevant and valuable to their personal choices and interaction with health care.
- Assure that patient communication strategies meet the needs of California's diverse populations with consideration to the following: technological sophistication, cultural sensitivity, educational opportunities, demographic differences, and sensitive health information.
- Enhance and leverage existing programs and community resources to engage in the consumer/patient engagement communication efforts.

The communications plan approach contemplates a number of strategic options for creating awareness and encouraging engagement with HIE services. The GE will establish a public campaign to ensure that consumers and patients are aware of how they can actively engage and benefit from the significant investment that has been made at the Federal and State level in the HIE infrastructure. Tactics include establishing a straightforward campaign and message architecture based on consumer, patient and provider research that clearly communicates "what's in it for me," supported by tangible Use Cases, using examples, personal stories, while leveraging the social media tools, e.g., Twitter and Facebook.

The second strategy is to follow a tiered approach for the introduction of HIE based on consumers' exposure and use of online health resources, determined by greater needs or interest in use of online healthcare tools. Below are some examples of target populations that would provide the most success in the outreach and education efforts in consumer engagement:

- Groups with special medical needs
- Highly mobile populations
- Those already familiar with using online tools, for example, patients with diabetes
- Users of PHRs
- Residents of senior centers
- People working outside the healthcare system that work with and may influence consumers to use EMR online healthcare tools (for example, teachers and social workers)
- Travelers

The third strategy is to address participation for the non-computer savvy population. California's population mix at large is very diverse in familiarity with technology. The communication strategy will use a mix of media for promotion of consumer engagement to reach across generational lines and be culturally sensitive.

The fourth strategy is to use role models and celebrities with a strong influence on the community. The workgroup proposes using role models to tell their story as part of the communication plan to educate consumers on HIE services and how the services can “save lives” and help drive adoption.

7.1.3 Tactics for Communications Plan, including Communication Channels

The workgroup proposes establishing a straightforward, research-based campaign and message architecture to 1) create a common vocabulary for education around complicated issues and 2) make clear the impact and benefits for a consumer. The communications plan will include message and proof points about privacy protections and checks/balances, and describe the opt-in process clearly in accessible language. The plan will create a visual mark for use by providers who are fully participating in HIE and meeting State technical requirements to reinforce the core components of the California HIE campaign.

The campaign will be structured in a tiered approach, by identifying and prioritizing the various groups to be targeted. In the first tier, early adopters and consumers with complex medical conditions will be targeted by utilizing appealing resources and tools to support making better choices.

Communication channels for the computer-literate and those with ready access to internet are numerous:

- Consumer-friendly website allowing the uploading of consumer friendly resources, tools and videos
- Electronic newsletters
- E-mail blasts and campaigns
- Social media tools
- Mobile applications for PDAs and smartphones
- Short message service (SMS) or “text” campaigns

The communications plan should specifically segment and address the Vulnerable and Underserved population with messages tailored to their concerns and delivered via channels that are accessible to these

populations. The emphasis on messages to this segment will be to develop trust and offer numerous in-person resources for engagement. For those without computer or internet access, communication and educational materials will be provided through the following channels:

- Public computer to log on (i.e. libraries, computers at doctor offices) kiosk;
- Senior center seminars and “ask the expert” sessions;
- Newsletters distributed via the public libraries, care settings including community clinics, community centers, and schools;
- Mass media channels such as TV/Radio/Billboard/Print Ads and direct mail; and
- Articles in local publications, small papers, and associations.

Another tactic of the communications plan is to identify and employ key figures in the consumers’ daily activities that can help influence engagement with HIE. Education materials about the importance of engaging consumers in HIE will be provided to these key individuals so they may act as influences on their local communities. These key figures are often providers, who can talk to patients about the value of HIE, where to go for more information on California’s efforts and how providers are participating. Parent-teacher organizations can help parents engage with HIE on their children’s behalf. Strong opinion leaders with credibility as role models will be leveraged to work as advocates and champions of HIE. Foundations and advocacy organizations working in healthcare will also carry the message to consumers.

7.1.3.1 Next Steps for Communications Plan

The Communications subcommittee proposes the establishment of an oversight council, potentially a subcommittee of the GE, to approve of the communication that is to go out to the health care and consumer population. The engagement of a consumer relations firm to survey the population, design the campaign, and detail out the communication methodologies is also recommended. It is recommended that the oversight council work with Human Resources to execute the plan. The workgroup proposes hiring a full-time project manager with administrative and budget management support to manage the efforts. Additionally, the oversight council would work collaboratively under the strategic oversight of a senior communications person at HHS.

7.1.4 Establishing a Marketplace of Innovation to Support Patient Engagement

The Patient Engagement workgroup determined a key strategy, as listed in section 6.1.2. above, for successful engagement of patients with HIE was to “encourage entrepreneurship and a burgeoning competitive marketplace for secure and sound HIE products and services that will encourage patient and family engagement in health care decision making.” The development of a set of HIE services provides an unprecedented opportunity to test new models, methods and tools to engage patients in shared decision making, reduce cost and improve both service delivery and quality.

As the evolves, the workgroup will explore how a marketplace of innovation can be supported to allow these tools to be demonstrated and used, tested, studied and established. The marketplace should establish a set of principles: that demonstrations respect and adhere to the privacy and security policies of the GE, that they leverage the HIE services to the fullest extent possible, that they be budget neutral so that risk may be borne by the organization demonstrating their product or service, and that they deliver value and help patients and providers in the shared decision making process. This marketplace would allow consumers to take full advantage of the expertise in California’s broad technology and venture capital communities.

7.1.5 Barriers to Patient Engagement with HIE Services

As part of the consideration of factors that could increase engagement with HIE, the workgroup examined potential barriers to engagement, or possible motivations why a consumer would choose not to participate in HIE. The workgroup identified a key barrier in a culture of mistrust that has been cultivated by the fear that the insurance industry punishes individuals for illness and high risk behaviors either by raising premiums or by dropping coverage. Concerns that insurance companies accessing personal health data, will use that data to deny benefits or coverage have contributed to a culture of reluctance to share medical records. The workgroup noted the possibility that the push for participation in health data exchange may run counter to the perception that sharing information about high risk lifestyles or behaviors may lead to loss of insurance status, penalties, or an inability to be insured if any loss of coverage occurs.

The workgroup will propose to the GE the workgroup study four groups: Medicare and Medicaid beneficiaries, those with employer-based insurance, direct-pay or privately insured individuals, and parents who control their children’s health data. The objectives of this survey would be to determine if there is a measurable fear of loss of insurance status if PHI is disclosed, if these perceptions differ among the groups, and if a customized communications message about how insurers are allowed to use PHI is needed.

8. Vulnerable and Underserved Populations and the Providers Who Serve Them

The Vulnerable and Underserved Workgroup determined the following principles: to address the unique needs of those populations and their providers, to conform, where feasible, to their specific needs, and to communicate to the providers who work with vulnerable and underserved populations and the patients themselves in a sensitive and appropriate manner:

To ensure that the HIE needs of the various programs providing critical services to these populations are addressed and met through the HIE services to be developed.

To ensure that communication strategies are developed that allow these populations and the programs that serve them to access HIE services.

The California HIE Operational plan strives to be inclusive of all vulnerable and underserved populations. Toward that end, the vulnerable and underserved workgroups investigated State agencies, advocates, public agencies and published literature with respect to identifying the unique needs of these populations and their information systems.

This heterogeneous population of patients, clients, and providers provides an enormous challenge for effective HIE, and one that is not easily resolved. In order to be truly inclusive, the Vulnerable and Underserved Workgroup recommends that the GE continues its investigation of how to best serve this population and their providers over the next 12 to 18 months. In addition to a complete inventory of social services, we recommend a representative of the GE join the California Mental Health Directors Association Information Technology Committee to assist their planning process and determine where the GE can provide sustainable services to them. The deliverables of that planning process would include the following:

Prioritization of HIE Services

Technical Assistance Plan for Ancillary Databases

Identification of Sustainable Services (Including Administrative Simplification)

Identification of Additional Financial Resources to Support HIE

The following information was gathered regarding these special populations. It is not intended to be either a complete or prioritized list, but is background information to be used to assist the planning process.

8.1 Consideration of Special Needs: Vulnerable Populations

The unique needs of each of these health care consumers are being assessed as related to HIE, specifically in terms of greater needs for enhanced privacy provisions, greater need to improve health literacy, need for administrative simplification, need for special tracking and/or quality measurements and need for greater coordination of care. The most common special need is for enhanced privacy protection, with greater need for coordination of care a close second. Many needed to improve their health literacy and administrative simplification, but few populations needed special tracking or quality measurements above and beyond what is anticipated for all Californians.

8.2 Integration Across Populations

For a seamless, holistic approach to consumer healthcare, a planning/strategy document should exist which describes all the protocols, intent, and how to, access clients data from multiple community support databases. This includes all of the State databases available from Public Health, incarceration facilities, social services, etc. With proper client permission it could also link other community support databases such as the faith-based communities, Community Action Agencies, hospice care facilities, and others.

There is a need for referral/treatment information linked between product and service providers within the county and across counties, providers of care for adults with substance abuse conditions, medical providers, social services, and pharmacies, while adhering to multiple confidentiality protocols and regulations. Travel between counties should not restrict electronic healthcare data flow.

8.3 Vulnerable and Underserved Children

The following table represents the specific child populations that must be considered for inclusion in HIE:

AB3632 Children	Children in Foster Care Programs	Children being raised by Low Income Grandparents
Children “at risk” for CPS issues and/or entering Foster Care	Community Care Facilities Residents	Criminal Justice
CCS-Qualified Children with Chronic Illnesses	Children with Developmental Disabilities	Fragile infants
Homeless	Impoverished/Poor	Food Stamps
CalWORKs	Lesbian, Gay, Bisexual, or Transgendered Children	Children with Mental Illness
Newborn Intensive Care	Children with Physical Disabilities	Transitional-Aged Children (emancipating)

For every segment mentioned above, Child Welfare Services will have specific needs for HIE functionality. Some of these issues that will require specific tailoring of the HIE services include:

- Provide access to holistic health data including information on physical, mental and behavioral health.
- Ensure quality of data coming from legacy systems, especially eligibility data, keeping in mind that Medicaid is the primary health care funding source for most children in foster care.
- Ensure capacity to exchange information between health care, social services, child welfare services, and the courts can support effective coordination and communication.
- Shortage of Medicaid providers causes overload for the few that do.
- Enabling mechanisms to overcome barriers to access, preventive services, shortage of mental health services, and lack of timely State assessments.

8.3.1 Children in Foster or Custodial Care

Service delivery and care can often be fragmented and uncoordinated in the current system. The workgroup determined a spectrum of important needs for consideration of children in foster or custodial care. Certain children may over-utilize health care services, while others may under-utilize services due to a number of factors, such as multiple placement changes within the foster care system, disjointed medical histories, lack of foster parent education/awareness, and a lack of coordinated access to medical and behavioral healthcare. Efforts to identify and treat foster children's health problems are complicated by their frequent changes in family placements, physicians, and schools. As a result of these changes, many foster children do not have a complete medical record, resulting in missing information about a child's allergies, immunization history, current medications, and health problems.

When a child is removed from the care of his or her parents, as in the case of foster care, complex issues arise including supervision of medical care, ability to authorize medical care, and ability to access confidential medical records. Licensed foster parents or relative caregivers may consent to routine medical and dental treatment for minors placed with them pursuant to a court order or with the voluntary consent of the person having the legal custody of the minor. The pediatrician should document the authority of a foster parent to give consent to medical treatment by obtaining a copy of the court order. Court orders routinely give child welfare services departments the ability to authorize routine medical care also. Parents who no longer have custody may still have the right to access their children's medical

records and be involved with health care decisions unless their parental rights have been terminated. In some (severe) cases, court orders can limit the parent's rights to participate in medical planning. Consent and supervision of medical care can be part of findings and orders made in court hearings. In addition, the juvenile judge and attorneys require timely access to current health information, and the information can become part of the court record and the California Court Case Management System. In particular, psychotropic medication is an area where the judge is required to approve treatment and changes in treatment. EHR systems that purport to manage consent for treatment and information access will need to be able to record these details.

It has been suggested that a variety of factors act as true barriers to care for these children. Information about health care services children have received and their health status before placement is often hard to obtain. In part, this is because children have had erratic contact with a number of health care providers before placement. In addition, social workers are not always able to review a child's health history in detail with birth parents at the time of placement and medical histories do not always follow a child from placement to placement. Foster care parents often have been given limited training in health care issues or in accessing the health care system. There are numerous instances of foster children being undertreated or given unnecessary treatment due to a lack of access to a complete medical record. Social workers often lack information about the type of health care services that children in foster care receive and are, therefore, unable to effectively oversee the amount or quality of care delivered. Increasingly complicated physical and mental health conditions in children in foster care make taking care of these children difficult, even for the committed physician.

8.3.2 Children in the Adoption Process

Records of children who are undergoing adoption proceedings or who have been adopted may need special privacy handling, as in a case where State law offers special protections for the identity of adoptees. Sensitive, closed and media cases may be additional types of constraints to privacy handling. The EHR systems should allow flagging of these data for special privacy protection. In some States, the pre-adoption record may need to be separated entirely from any post-adoption record by using distinct patient identities. In addition, many children adopted through the foster care system may have multiple sources of health care insurance, including Medi-Cal, so this information will be available via HIE.

8.3.3 Guardianship

The identity of a child's guardian and guarantor can become complicated outside the bounds of the "typical" 2-parent household. The EHR system must provide the flexibility to indicate the broad variety

of adults in the child's life who may play some role in medical or financial decision-making. The system should draw a distinction between the patient's guardian and his or her financial guarantor. In those cases in which a court has appointed a guardian for a minor, the ability of the guardian to consent to medical treatment depends on the type of treatment being sought and the scope of authority the court has granted. If more than routine care is required, the pediatrician should document the authority of the guardian to give consent by obtaining a copy of the official certified letters of guardianship. The EHR system should support this record-keeping. EHRs need to have the ability to identify and to change guardian status easily for children in foster and guardian care.

8.3.4 Emergency Treatment

When EHR systems support the recording of consent and assent for treatment, they should be flexible enough to allow for the emergency treatment of minors, in which the parent or legal guardian may be absent, and the usual procedures for consent will change.

8.3.5 Management of Consents and Authorizations

A consent or authorization includes patient authorization for re-disclosure of sensitive information to third parties. Consents/Authorizations for printing should include appropriate standardized forms for patients, guardians and foster parents. The system must appropriately present forms for adolescents according to privacy rules.

Some types of health information, including information on substance abuse treatment, requires consent to be shared with other systems. When dealing with children in foster care, it is good policy to consider requiring assent of adolescents to sharing health care information. It would be useful if the structure of the record could include this consent/assent.

8.4 Vulnerable and Underserved Adults

The following table displays the categories of vulnerable and/or underserved adults considered for this analysis:

Aging / Long Term Care	Chronic Illness (i.e. HIV/AIDS, etc.)	Community Care Facilities Residents
Criminal Justice/Probation	Adults with Developmental Disabilities	Homeless Adults
Immigrants	Impoverished/Poor	Food Stamps
Social Security Income only	CalWORKs/TANF	Tribal TANF
Integrated Case Management Recipients	Lesbian, Gay, Bisexual, or Transgendered Adults	Adults with Mental Illness

Migrant Farm workers	Military Families	Adults with Physical Disabilities
Adults with Substance Abuse Conditions	Limited English Proficiency	Single Women with Young Children
Tribal Populations	Rural Populations	Unemployed/Underemployed
Veterans	HIV/AIDS population	ESL and non-English speaking patients
Low-income women vulnerable for premature birth or other pregnancy complications	Undocumented Immigrants	Documented Immigrants
Dual Eligible beneficiaries (Medicare/Medicaid)	Medi-Cal Managed Care beneficiaries	Uninsured/ Limited Benefits
Privately Insured (Individual Market)		

As is the case with Vulnerable and Underserved Children, the unique needs of each of these health care consumers are being assessed as related to HIE, specifically in terms of greater needs for enhanced privacy provisions, greater need to improve health literacy, need for administrative simplification, need for special tracking and/or quality measurements and need for greater coordination of care. Similarly, the most common special need is for enhanced privacy protection, with greater need for coordination of care a close second. Many needed to improve their health literacy and administrative simplification, but few populations needed special tracking or quality measurements above and beyond what is anticipated for all Californians.

8.5 Consideration of Special Needs : Providers to Vulnerable Populations

Each of the following groups are considered for their general issues/concerns, links with public health data systems, integration of information across case management, social services providers and Electronic Health Records, privacy protections, patient engagement/ outreach/ health literacy, medication management, population management, quality measurement, care coordination and administrative simplification. An approach to each provider group is described below.

8.6 Mental and Behavioral Health Providers:

Federal and State legislation²⁴ requires that detailed clinical information is integrated with billing and eligibility information, and tracked by clients, claims and providers. Workflow must be tracked and decision support must exist to remind clinicians to select appropriate services and to provide all necessary

²⁴ INFORMATION TECHNOLOGY COMPONENT AND TECHNOLOGICAL NEEDS PROJECT PROPOSALS. City and County of San Francisco Department of Public Health, Community Behavioral Health Services, Mental Health Services Act (MHSA). December 17, 2009)

documentation to support billing. Regulations require clinicians to use best practices to measure outcomes of care, and to fully engage consumers in their health care and personal health record.

Challenges associated with mental health provision include that the behavioral health population is migratory. For the same patient and across Statewide behavioral healthcare providers, there are multiple and distinct registration information profiles simultaneously in existence. There are no Statewide standards for date-stamping data records, complicating follow-up care. Finally, there is a proliferation of local county specific databases designed for programs such as Criminal Offenders with Mental Illness, Drug-Court, Computer Resource Allocation Inventories, and others that do not cross-reference.

In California, County mental health departments are responsible for the mental health managed care program. As such, the fiduciary relationship is between the State and the County mental health systems. There is not a direct fiduciary relationship between the State and mental health providers that are not operated directly by the county; instead, counties contract with private mental health providers. Due to this administrative structure, it is critically important that County mental health agencies be part of the “provider” conceptualization, as well as identified as having important administrative functions. The GE will consider it critical that provider networks are considered with respect to the counties they support with mental health services.

This heterogeneous population of patients and providers provides an enormous challenge for effective HIE, and one that is not easily resolved. The Vulnerable and Underserved Workgroup recommends that the SDE continues its investigation of how to best serve this population and their providers over the next 12 to 18 months. We recommend a representative of the SDE join the county mental health associations Health IT Committee to assist their planning process and determine where the SDE can provide sustainable services to them. The deliverables of that planning process would include the following:

- Prioritization of HIE Services

- Technical Assistance Plan

- Identification of Sustainable Services (Including Administrative Simplification)

- Identification of Additional Financial Resources to Support HIE

8.7 Rural Providers

Covering more than 50% of the California landmass, yet only 10% of its residents, California’s 63 Rural Hospitals, 260 Rural Health Clinics, 70 Tribal Clinics, more than 230 community federally qualified

health centers (FQHCs) and community health centers, and approximately 1600 high-volume Medi-Cal providers run the gamut from having no information Technology infrastructure to having the most successful health information exchanges in the State. Most rural providers share common issues: a lack of broadband access, technical competency and IT workforce shortages, financial strain and limited resources. Virtually all Rural Health Clinics and FQHCs in rural areas are eligible for Medi-Cal EHR Incentive Payments, as are two thirds of the rural hospitals under the current NPRM, in addition to most physicians. As of this writing, the workgroup believes that Critical Access Hospitals are excluded from CMS reimbursement, but can get costs of adoption reimbursed after the fact.

The scarcity of specialists in these medically underserved communities compel patients to rely on technology such as telemedicine and home health monitoring to receive timely and appropriate care. As such, the establishment of broadband infrastructure to these communities is an essential requirement to resolve health care disparities. The GE will work closely with the California Telehealth Network to provide broadband to all rural hospitals in California and promote integration with EHRs.

Meaningful use is achieved only through the capture and exchange of information between pharmacies, labs, imaging facilities, physicians, clinics, hospitals and long-term care facilities. It is unlikely that the 63 rural communities anchored by their respective hospitals will form these local exchanges without direct assistance, guidance and intervention from the GE. The GE will assist in the planning, implementation, standardization and sustainability of local exchanges based in every rural hospital in the State that wishes to participate, and, where possible, apply for the 90/10 match from CMS to fund this assistance to medically underserved areas and predominantly Medi-Cal providers.

Equally essential, if not more, is the availability of working capital to build the necessary infrastructure for meaningful use in Critical Access Hospitals, who may have to wait up to five years for full reimbursement of their HIT expenditures. Non-profit and public facilities may potentially access loans from California Health Facilities Financing Authority (CHFFA), but many rural facilities are not-non-profit and need another financing alternative. Such an alternative may come from United Health Care (UHC). As one condition of the privatization of United Health Care a program was created to provide capital for the reduction of disparities in health care. The UHC program could fund the costs of issuance of a low interest rate \$10,000,000 loan fund supported by a bond initiative. Under a separate grant, UHC would also be able to cover the costs of planning this initiative. In order to receive the low-cost loan, eight to ten eligible hospitals would need to be ready to move forward on health IT adoption. This work has been begun by the Critical Access Hospital Network, UHC, the California Hospitals Association (CHA)

and California State Rural Health Association (CSRHA). The GE will assist in the timely implementation of the UHC bond program, which expires at the end of 2010, and to support the CHFFA program.

Rural patients are likely to find it difficult to travel for healthcare, have limited access to broadband and fewer financial resources. As part of the rural HIE infrastructure planning, the GE will promote the use of patient kiosks, physician email and messaging and self reporting via telehealth and home health monitoring.

8.8 Mobile Clinics/Mobile Units:

Mobile clinics require the ability to connect at intervals, and store and forward information when they have internet access.

8.9 Mobile and Standing Blood Banks

Blood banks have been on the forefront of Health Information Technology, yet have limited financial resources. The blood banks are required to report some positive test results to the Department of Health in the county where the donor or patient resides, which could be facilitated through the HIE. Blood banks also need to interface with hospitals EMR when providing autologous or reference lab services for patients. Blood banks are exempt from certain HIPAA regulations, so data exchange may be permissible in ways that are not common to the rest of the HIE, as long as compliant with State privacy and security guidance. These differences must be carefully considered.

Other features of the HIE that are needed by blood banks are timely access to data (such as in the case of a product recall, and the ability to track autologous patients as they change hospitals and doctors.

8.10 School-based Health Care (SBHCs):

The primary challenge will be that SBHCs are operated by different kinds of agencies: some run by community health centers, some by hospitals, and others run by school districts. Note that most SBHCs provide care to very poor, disenfranchised populations which are often uninsured.

8.11 Public Hospitals and Emergency Rooms

Many vulnerable underserved patients are treated in acute settings, especially the Emergency Department. This population has a unique challenge for data exchanged through the HIE from these settings because traditional identifiers such as social security number are often absent. There is a high percentage of non-English speakers, low health literacy levels, and patients have limited access to private

There is a strong need for documentation of social/community resource needs/utilization in the record which is accessible to medical providers to facilitate coordination of care and to maximize use of available community based support.

8.12 Community Health Centers and Public Clinics

Community Clinics and Health Centers share many of the needs of the public hospitals and emergency rooms. In addition to financial constraints, one of the key challenges for clinics is the mechanics of including uninsured and homeless patients in HIE.

8.13 Long Term Care/Skilled Nursing Facilities

Some older adults have professionals or family members acting as their conservator or as their Power of Attorney for Health Care; in those situations, the person holding the right to make medical decisions would need to be included in decision making, as well as having access to the information.

Given their high degree of acuity, their high number of medications, medication interaction effects and their vulnerability to side effects of medications, in this age group, it is particularly important for integration of medical, pharmaceutical and mental health information of medications, ER usage, number of medical hospitalizations, number of chronic medical conditions, number of doctors, number of doctor visits, length of medical hospitalizations.

8.14 Indian Health Services

There is a strong need for Tribal and Urban Health Programs to interface with RPMS (IHS system) and need to meet stringent IHS reporting requirements, including GPRA reporting. There are 638 small/independent Tribal Health Programs in rural and isolated communities, which are hard to reach and have high provider turnover. There is little support for the Tribal and Urban Health Programs in CA by IHS for non-RPMS EHR implementation despite large amount of Federal funding for the IHS.

8.15 Veterans' Administration facilities/DOD

Integration with the VA's Vista system and My HealthEVet is essential.

8.16 Dentists

The biggest issue for dentists are 1) they're far behind medicine in the adoption of HIT and EHRs; 2) there is currently no certified electronic dental record; 3) there are no nationally-accepted and validated dental quality measures, so although dentists are included as eligible providers in the meaningful use

NPRM, there were no dental-specific quality measures proposed for this reason; 4) there has not been much interest to date on the part of EHR vendors to develop interoperable (medical and dental) EHRs.

8.17 Community Care Facility Licensees

Licensees accept clients who are placed by various placement agencies, such as Corrections, Regional Centers, Probation, Child Welfare Services and having access to past health information is vital in determining the medical needs of the client

Many clients who live in CCFs have chronic medical conditions. Access to health information may provide improved outcomes for clients. Some licensees do not have access to the Internet, and facilities located in rural areas may not have local access to health care services. Licensees currently have no known access to health information databases. However, licensees who serve children are required to have proof of immunizations on file. All facility categories maintain confidential health information.

8.18 Correctional Facilities

Under direction of the Receiver, The California Department of Corrections has built an electronic clinical data repository which warehouses the medical records of its inmates, connecting its 33 facilities to laboratory and pharmacy services, which are available through a portal to its 6000 healthcare providers. This repository is used for disease management and tracking programs. The SDE needs to assist in the integration of this system into State HIE services, determine whether this system can be used to assist their providers to achieve meaningful use, and facilitate shared services between the programs.

8.19 California Welfare Services:

Need to access current information to effectively serve CWS families without learning more detail than needed.

In-Home Supportive Services Program (IHSS)

Case managers in IHSS, APS, MSSP and other care programs would benefit in having access to information to ensure smooth transitions between hospital and other institutional settings and in-home and community based settings to assist in tracking and managing chronic care conditions, health and social service needs.

8.20 Vulnerable and Underserved Insurance Providers

Many safety net providers focus on the uninsured and underinsured which provides low reimbursement. There is low adoption of EHRs by participating providers, and not all providers have computers or access to the internet. Many practices lack time and/or financial resources to evaluate, select, purchase, implement and maintain EHRs. The workgroup proposed the following recommendations:

- single point of access for all services, both medical and social
- universal documentation of social/community resource needs/utilization in the record which is accessible to medical providers to facilitate coordination of care and to maximize use of available community based support.
- single credentialing body for physician credentialing
- use of One-E-App for all social services.

A centralized source of information regarding all medications prescribed/used by members. Rx info accessible to providers and members would facilitate avoidance of polypharmacy, and other medication errors and improve patient compliance

Provide an Individualized Care Plan that is available across the continuum (ideally, one which could be updated by providers at each point of care). This should be accessible by practitioners as well as health plan or physician group case managers to aid in coordination of services and avoidance of duplication of service.

8.21 Public Health

The difficulty of establishing robust health information exchanges (HIE) remains a significant challenge. For public health, the full benefit of Health IT is the interoperability and exchange of data at the community level. CDPH must be able to transmit and integrate data across multiple internal and external data sources and transform these data into meaningful information in order to prepare for and respond to emergencies, diseases, outbreaks, epidemics, and emerging threats. There remains a need for comprehensive and integrated communications tools supported by IT infrastructure to work collaboratively and in real time among CDPH program areas. External partners and the public could effectively share and disseminate information necessary to achieve timely public health interventions and response.

8.21.1 Need for Standards

CDPH must have the ability to guarantee secure, reliable, and rapid information access and communication capabilities essential to respond rapidly to public health emergencies within the evolving public health environment. This may require both identifiable and de-identified data that can be linked, integrated and used for public health prevention and quality of care improvements. This will allow full use of geographic software to provide useful data for communities that can be understood by providers and the public.

California statute requires reporting of many diseases and conditions to the California Department of Public Health which places a significant burden on providers and hospital systems, as this reporting is currently performed through manual processes that do not yet leverage the potential that can be achieved with electronic HIE. Many of these items are beginning to be captured in the Continuity of Care Document (CCD). Although the CCD does not encompass all current statutory reporting requirements, it does include current medical problems, procedures, family history, social history, payers, advance directives, alerts (allergies, adverse reactions), medications, immunizations, medical equipment, vital signs, functional status, results, encounters, and plan of care. Thus the CCD serves as a solid basis that, if implemented within California HIE, would likely relieve significant work load requirements currently experienced by both providers and local and State public health departments. Public health must identify its priorities that will benefit Californians as HIE is implemented across the State. The CDPH Data Policy Advisory Committee recommends a focus on the infrastructure necessary for CDPH and local health departments to be a part of a collective HIE.

8.21.2 A Key Priority: Plan for California's Immunization Registry

As an example of one of the key targeted areas for Health IT priorities, we describe a plan for California's immunization registry. Similar efforts will be in place to achieve effective meaningful use through lab exchange, e-prescribing, continuity of care records and tuberculosis registries.

At the present time, the State of California's Statewide immunization registry consists of nine regional and one county registry. The State has a permissive registry model where participation is encouraged, but not required. Providers in public sector clinics are required to participate, but private providers are not and have a significantly lower use rate. One of the largest providers, Kaiser Permanente, does not participate in the Statewide registry system and remains an ongoing challenge. There are four software systems currently utilized in the Statewide registry system: CAIR, utilized by 7 of the 9 regional registries, and separate systems in the mid-San Joaquin Valley, the San Diego region, and Imperial

County. The registries are sharing data electronically with many provider groups throughout the State. As in the rest of the United States, the majority of electronic immunization data exchanges utilize flat files. Real time bidirectional HL7 data exchange is occurring on a limited basis between a few provider organizations and the San Diego registry. The immunization registries offer a variety of functions, such as providing California school forms and inventory features, which currently are not included in electronic health record systems.

8.21.3 The Vision

We envision a Statewide immunization registry that supports bi-directional interfaces in real-time, near-time, and batch delivery modes for healthcare providers caring for adults and children. The regional immunization registries must also support data exchange across all regions. Improved registry functionality will allow providers to enter information as well as retrieve up-to-date immunization records in their native electronic health record, disease registries or the immunization registry.

8.21.4 The Need

To prepare for maximum leverage of Medicare/Medicaid stimulus funds, the State of California will lead an effort to publish detailed specifications and a process to support the Statewide registry. The HITECH strategic planning efforts allow for an integrated plan that promotes workforce training to provide on-the-ground registry support at the local and regional levels. In addition, through committing to Medicaid program implementation, we will work with stakeholders to include meaningful use criteria that create incentives for immunization registry participation. Support for new EHR software purchases must also support bi-directional interfaces and batch exchanges for use with the Statewide registry to qualify for HITECH funds. California's Regional Extension Center will support this effort by providing template contracts and requirements for EHR purchases, project plans and technical assistance to ensure that bi-directional interfaces and batch exchanges with immunization registries are utilized.

Through the use of health information technology, public health informatics can help achieve its overall goals by monitoring health outcomes, increasing outreach for prevention services, and identifying targeted interventions in the future for each program within public health. There are currently over 300 programs in public health, including:

California Automated Immunization Registry (CAIR)

Reportable disease registries (CalREDIE)

Lead exposure (RASCCLE)

Genetic Screening Information System (SIS)

California Cancer Registry (CCR)

Lab Data Interchange for Microbial disease

Lab Exchange Systems (Star LIMS)

Vital Records (AVSS and EDRS)

8.22 Ancillary Systems for the Vulnerable and Underserved

It is estimated that California has more than 150 disparate databases that could potentially benefit from HIE. Where possible, the HIE will achieve bidirectional communication with as many of these as feasible. The GE should create a complete inventory of these systems, prioritize them and participate in life-cycle

8.23 HIE Communication and Outreach to the Vulnerable and Underserved

The committee recommends that education materials are developed for all populations with standardized core messages and graphic design, adapted for all v/u populations in consultation with advocacy groups and not printed or distributed, but made available to the advocacy groups and providers through the web as printables and handouts.

8.24 Privacy Concerns of Vulnerable and Underserved Populations

The following issues were raised by the Vulnerable and Underserved Committees related to privacy concerns of these populations. These concerns will be considered by the GE and accommodated where feasible.

State law related to HIV and social security number use,

High sensitivity of mental health and addiction issues.

If SBHC is run by school district, it will operate under FERPA, not HIPAA. If SBHC is run by CHC, then it operates under HIPAA. The FERPA-HIPAA interface in schools is very complex. Also, adolescents often receive sensitive services as outlined in CA Minor Consent Laws. These services may be provided without parent consent and confidentiality must be protected.

Challenge of selecting a unique ID when traditional identifiers such as social security numbers are absent

Standard HIPAA acknowledgement document signed by parent upon admission. Parents not always advised of info transfers.

Clients may not want information shared on a global level. Client may want to protect basic information like diagnosis. More difficult to develop standardized criteria for disclosure that respect the client's desires. Mental Health, Substance Abuse, and Medical confidentiality regulations confound the smooth exchange of information, sometimes within the same system/organization.

Family member need or desire to access health information

There may be HIPPA requirements that preclude licensees from obtaining confidential health information.

There may be statutory change required to allow licensing staff access to health information

Method for member identification needs to ensure that the appropriate member is being identified for data sharing so privacy protections are not violated.

CWS Social Workers have access to health information for children placed in Foster Care. They may also need information when investigating suspected child abuse in order to make quality recommendation to the courts. This requires parent/guardian consent, which can be difficult to obtain.

Foster parents are authorized to act on behalf of the child to schedule medical appointments and ensure access to medical services. Courts and social workers (and counties with PHNs) oversee this function as well.

HIPPA is generally misunderstood and serves as significant barrier for the necessary exchange of health information both intra and interagency communications

Foster parents are authorized to act on behalf of the child to schedule medical appointments and ensure access to medical services. Courts and social workers (and counties with PHNs) oversee this function as well.

Some older adults have professionals or family members acting as their conservator or as their Power of Attorney for Health Care; in those situations, the person holding the right to make medical decisions would need to be included in decision making, as well as having access to the information.

EHRs will need to develop multiple levels of security and to facilitate selective access to different components of the medical records. These permissions will need to change as an adolescent ages. Once the adolescent reaches age 18, access will need to be reassessed and systems developed to ensure that the young adult controls access to his or her EHR.

EHRs need to address unique privacy issues including adolescent privacy, foster and guardian care, and consent for treatment. EHRs need to allow for differential treatment of certain protected information as needed.

HIPAA distinguishes between emancipated and unemancipated minors regarding disclosure to third parties. Emancipated minors, like adults, must be given access to their health information and medical records, as well as the ability to obtain copies and to request corrections. For unemancipated minors, the rule provides for parental control of information flow.

Adolescent Privacy: Laws about age of consent vary from State to State and according to presenting problem. Adolescents who present for treatment of mental health disorders, for example, may consent to their treatment at an earlier age than the age of majority in most States. Some States also have laws regarding parental notification whereby interpretation is based on the patient's age and presenting problem. Practices that serve adolescents typically have policies with respect to what portion of an adolescent's care should be handled with special privacy protections (e.g., in some jurisdictions, the adolescent must give explicit permission for the parent to review his or her records). These privacy protections may require the flagging of protected information. Therefore, EHR systems should support privacy policies that vary by age, and according to presenting problem and diagnosis and be flexible enough to handle the policies of individual practices. Furthermore, if an EHR system handles record-keeping for consent for treatment, it should provide for the recording of assent for treatment (from an underage adolescent or child) combined with parental informed permission as well as consent for treatment (from an adolescent) combined with a record of parental involvement. The separation of the patient's consent and the parent's or guardian's consent is particularly important in the area of testing for drugs of abuse. Pregnancy is another area in which the records of patient and parental consent, assent, and permission may be less straightforward than in adult care.

State laws vary on the treatment of adolescents' rights to privacy regarding certain sensitive health information (e.g., pregnancy and sexually transmitted diseases) and parental notification. Adolescents' and parents' legal rights to access medical records vary and may differ depending on the content, such as psychiatric issues or reproductive health.

8.25 Metrics and Measurements for Vulnerable and Underserved Populations

Behavioral Health and Social Services:

Attendance at regular meetings with stakeholders,

The completion of an operational plan in 12-18 months and

The identification of funding streams to sustain the plan.

For Rural and Indian Health Services:

The number of communities that enter and complete the RHITC program.

For all other vulnerable and underserved populations:

Drawdown of meaningful use incentive payments by providers serving the vulnerable and underserved populations.

Comparing with expected population distributions

Outreach to provider groups that are not well represented in MU and HIE.

9. Legal and Policy

California began its privacy and security work related to health information exchange as a participant in the Health Information Security and Privacy Collaboration operated by the Research Triangle, Inc. on behalf of ONC. In 2007, at the direction of the Secretary of Health and Human Services the California Privacy and Security Board was created and charged with recommending the best privacy and security solutions for the advancement of HIE in California. The work of the CalPSAB has been complex and difficult at times, but has set the foundation for process and has outlined the objectives for the future.

Over the past three years, the CalPSAB has researched, evaluated, and vetted a number of issues. Privacy and security baseline standards were established in early phases of work including principles for privacy and security and scope of the potential rules. Subsequently, issues surrounding consent options were assessed. The CalPSAB ventured through several scenarios, including e-prescribing, laboratory, mental health, and emergency department scenarios, to comparatively analyze the consent options. To date, the consent option decision remains split among disparate stakeholders in the health care community.

The complexity of the consent discussion exposed other areas of required analysis, most prominently, limiting the use of health information to those appropriate. The CalPSAB conducted research and analysis of three specific scenarios, secondary uses of health information for e-prescribing, laboratory results, and emergency department. The findings of the analyses shed new light on issues that would need to be resolved before privacy and security standards could be established. The findings also supported the need to balance the consent option with the ability to control the flow of data and the security controls in existence to safeguard the data.

CalPSAB's past couple years of work has been foundational to setting the stage for privacy and security for HIE. As you will see in the next sections, CalPSAB's continued progress is dependent on four main bodies of work:

- Consent to use health information in an HIE
- Access control standards in an HIE
- Limiting to appropriate uses of health information
- Segregation of sensitive health information

These essential components of privacy and security hold the key to successful electronic exchange of health information by fostering trust of all its participants and users. Determining appropriate use of

health information will create reasonable limits to data use and sharing. The consent option ensures patient awareness of their information that is exchanged and will provide patient's with reasonable control over the exchange of their own health information. Access control standards will provide a standard set of criteria in which to control the flow of health information throughout an HIE and will embed reasonable data access limitations that minimize risk of misuse and inappropriate disclosure. Segregation of health information will allow for specialized protection of sensitive health information.

Over the next few years, the E-Health Policy Branch will work closely with the GE to develop, promote, and enforce a comprehensive set of rules for California health care industry stakeholders exchanging electronic health information. The E-Health Policy Branch guidelines will complement the HIE GE's policy guidance (HIE Policy Process) to create a standard set of legal, technical, business, and privacy and security rules for health care industry stakeholders performing health information exchange in California. California entities utilizing HIE services will be required to operate under these common set of rules.

The cutting-edge nature of health information exchange requires a somewhat fluid and iterative process for the development of new privacy and security rules. The plans to create standardized rules through the various efforts facilitated and overseen by the E-Health Policy Branch are discussed below (See Attachment X: CalOHII – E-Health Policy Branch Privacy and Security Work Roadmap).

The E-Health Policy Branch supports and facilitates five main areas of HIE privacy and security work:

- ***Privacy and Security Harmonization*** – The E-Health Policy Branch provides legal recommendations for harmonization of State and federal privacy and security laws. Through the CalPSAB Legal Committee process California laws are identified and examined for barriers to HIE. Where barriers or gaps are discovered, recommendations are made to the Secretary of Health and Human Services.
- ***Privacy and Security Guidelines*** – The E-Health Policy Branch oversees the development of interim and final guidelines that facilitate and support HIE in California. Privacy and security guidelines are documented, vetted, and refined over time to ultimately create the standards for all California health information exchange participants.
- ***CalPSAB*** – The CalPSAB was established by the Secretary of the California Health and Human Services Agency (CHHS) to provide private and public collaboration to address and coordinate health information exchange privacy and security efforts in California. The

CalPSAB is a forum facilitated by the E-Health Policy Branch to vet guidelines and demonstration projects through public and private stakeholders.

- ***Demonstration Projects*** – A variety of projects will provide focused testing on California HIE privacy and security guidelines, specifically in areas where health care industry stakeholders have illustrated polarization on issues that continue to be unresolved. These projects will also test guideline implementation strategies for viability among a broad array of stakeholders.
- ***Education*** – The E-Health Policy Branch provides consumers and providers with education materials to support the consumer and provider community as California moves forward with the adoption of health information exchange.

9.1 Privacy and Security Harmonization

CalOHII has inventoried and analyzed the existing State laws in California that apply to privacy and security of personal health information. CalPSAB is finalizing a set of initial priority targets to harmonize existing policies and requirements that may be interpreted differently, are not consistent with one another, and may not be uniformly applied. CalPSAB has established a committee structure with a flexible multi-year agenda of tasks to endeavor to resolve the issues being identified.

California believes that it is imperative to develop widely-accepted legal and business rules with uniform consent forms and procedures that will enable the exchange of health information for clinical treatment purposes while assuring confidentiality and security of the information. The conflicting understanding of the law impacts the existing mechanisms and procedures in California and put at risk the efficient and effective exchange of health information.

CalPSAB and GE will collaborate to ensure that Statewide policy guidance and contracting requirements for participants in HIE harmonizes with California law, court orders, regulations, guidelines, and federal law and well as coordinate California's requirements with evolving rules at the federal level. As an additional goal, the HIE Policy Process will strive to harmonize disparate requirements of neighboring States to enable efficient administration.

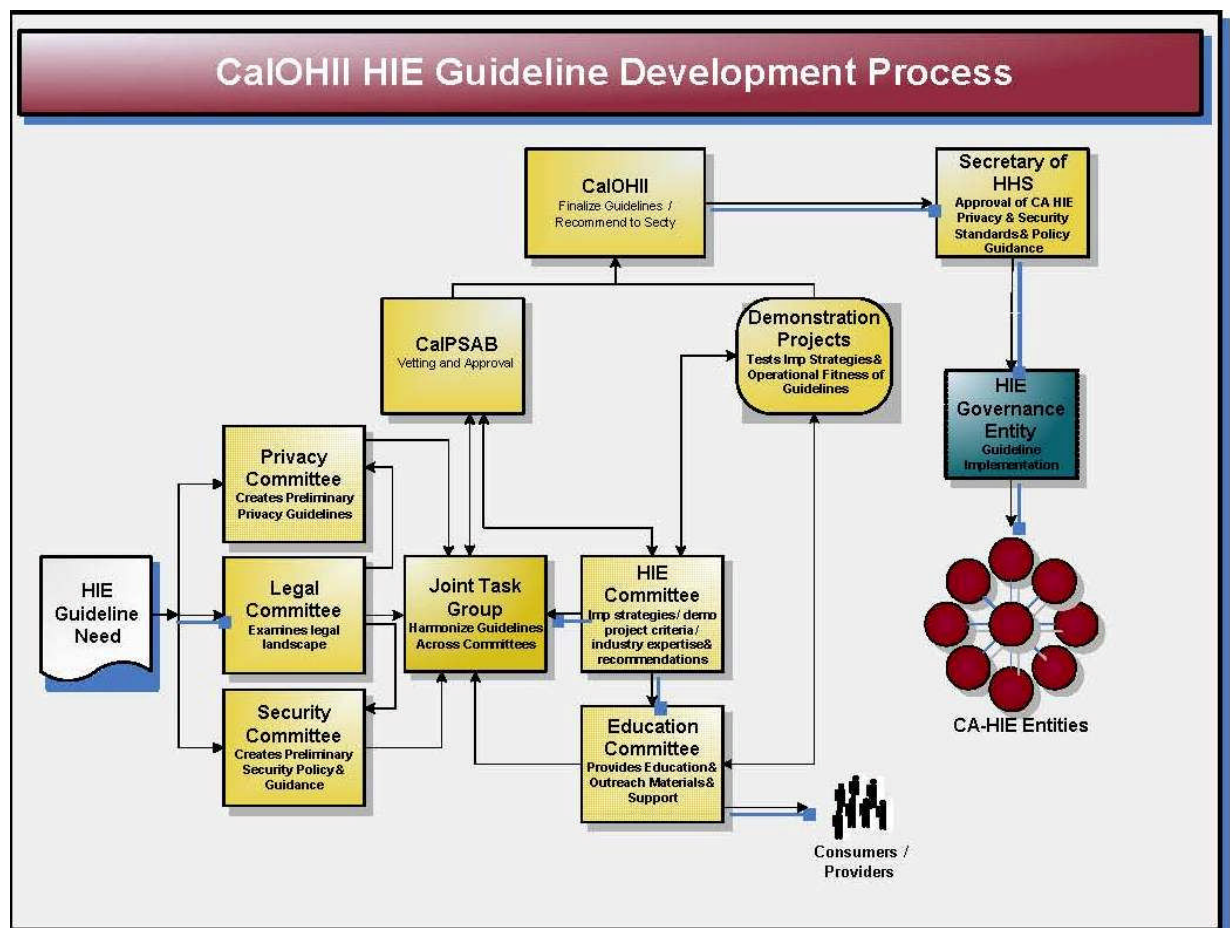
9.2 Privacy and Security Guidelines

The E-Health Policy Branch produced a preliminary set of Privacy and Security Guidelines in 2009 based on existing State and federal legal requirements. The E-Health Policy Branch has included privacy and security provisions of HITECH, HIPAA Privacy Rule, HIPAA Security Rule, Confidentiality of Alcohol

and Drug Abuse Patient Records Regulations, California law, and the HHS Privacy and Security Framework in the preliminary guidelines and will continue to update the guidelines as new guidance is provided by the Federal government. The guidelines will initially apply to entities in receipt of the ARRA funding or services provided from entities resulting from the ARRA funding.

The preliminary guidelines have been vetted through the CalPSAB process and constantly evolve as issues emerge and are resolved. The E-Health Policy Branch will continue to work through the CalPSAB process to resolve issues and progress to standardization of privacy and security rules. The guideline process is comprised of a variety of efforts including committees, task groups, joint task groups, and demonstration projects. See the process diagram below that illustrates the CalOHII Guideline Development Process.

Final recommendations regarding health information exchange privacy and security guidelines will be submitted for approval by the Secretary of CHHS. See diagram below of CalOHII HIE Guideline Development Process.



9.3 CalPSAB

The California Privacy Security & Advisory Board (CalPSAB) is a broad coalition with active members from the major health systems, consumer advocates, insurers, medical groups, community clinics, employer groups, public health and health information organizations (HIOs) as well as professional associations who represent these stakeholder groups. The Board is tasked to develop and recommend privacy and security policies for California HIE that promote quality of care, respect the privacy and security of personal health information, and enhance trust. CalPSAB has five committees that address diverse HIE privacy and security issues: Privacy, Security, Legal, HIE, and Education. The committees are collectively responsible for analyzing issues, developing and evaluating the effectiveness of alternate solutions, and presenting proposals to the CalPSAB.

CalPSAB recommends methods to harmonize State and federal privacy and security laws in order to support compliant HIE. The Legal Committee, specifically identifies and reviews State and federal privacy and security laws for barriers to HIE. Recommendations made to the Secretary of Health and Human Services are intended to bring California's laws into a congruent legal framework. To remove barriers to HIE, CalOHII will ultimately develop legislative proposals to amend laws or create regulations to be approved by the Secretary.

9.3.1 Privacy Committee Activities

The Privacy Committee is responsible for the coordinated analyses of privacy issues. The priority of each of the activities depends on current issues, coordination with other committees and task groups, and resource availability. Over the next five years, the Privacy Committee plans to proceed with the following activities:

Privacy Committee Activity	Est. Timeframe
Privacy Baseline Assessment and Determination	Oct 2007 – Apr 2008
Applicability	Jul 2008 – Mar 2009
Consent Option Analysis (Mental Health, Emergency Department, Laboratory, e-Prescribing)	May 2008 – Sep 2008
ePrescribing Secondary Use	Jan 2009 – Apr 2009
Laboratory Secondary Use	Mar 2009 – Jun 2009
Verification of Identity	Jun 2009 – Dec 2009
Emergency Department Secondary Use	Apr 2009 – Aug 2010
Sensitive Health Information – Define, Use / Purpose Limitation	Oct 2009 – Jul – 2010
Care Management Secondary Use	Nov 2009 – Aug 2010
Emergency Department Use / Purpose Limitation	Aug 2009 – Aug 2010
Health Care Operations Use / Purpose Limitation	Mar 2010 – Jun 2010
Public Health Use / Purpose Limitation	Jul 2010 – Dec 2010
Quality Reporting Secondary Use	Oct 2009 – Aug 2011

Privacy Committee Activity	Est. Timeframe
Personal Health Records / Patient Access	Feb 2011 – Dec 2011
Clinical Summary Use / Purpose Limitation	Feb 2011 – Apr 2011
Research Use / Purpose Limitation	Jan 2012 – May 2012
De-Identification of Health Information	Jan 2012 – May 2012
Payment Use / Purpose Limitation	May 2012 – Aug 2012
Appropriate Use Limitation	May 2012 – Aug 2012
Health Care Oversight Use / Purpose Limitation	Sep 2012 – Feb 2013
Required by Law Use / Purpose Limitation	Apr 2013 – Jul 2013
Law Enforcement Use / Purpose Limitation	Jan 2014 – May 2014
Decedents/ Coroners Use / Purpose Limitation	Jan 2014 – May 2014
Government Functions Use / Purpose Limitation	May 2014 – Sep 2014
Employer Use / Purpose Limitation	Oct 2014 – Jan 2015
Marketing Use / Purpose Limitation	Oct 2014 – Jan 2015
Judicial Administrative Use / Purpose Limitation	Jan 2015 – Apr 2015
Health and Safety Use / Purpose Limitation	Jan 2015 – Apr 2015
Worker’s Compensation Use / Purpose Limitation	May 2015 – Aug 2015
DIB / SSI Eligibility Use / Purpose Limitation	May 2015 – Aug 2015

9.3.2 Legal Committee Activities

The Legal Committee is responsible for recommendations to harmonize State and federal laws related to privacy and security of health information. The Legal Committee provides direct input to all other committees to help ensure that the laws are accurately and consistently interpreted throughout the process of issue formulation, alternative discussions, solutions determination, and implementation.

Where impediments or gaps exist in the legal landscape that supports HIE in California, legal recommendations will be made by the Legal Committee to resolve these problems. Recommendations include harmonization of State law and constitutional amendment, court case findings, and federal law.

The activities for the Legal Committee include critical legal fixes to standardize definitions, interpretations, and contractual obligations, such as the Data Use and Reciprocal Support Agreement (DURSA).

Legal Committee Activity	Est. Timeframe
Assess DURSA for applicability in California based upon legal risks and needs.	Mar 2010 – Jul 2010
Identify HIPAA provisions that are not clearly expressed in California law.	Mar 2010 – Dec 2010
Identify “Research” provisions in California and Federal law and harmonize; Define “Clinical Researcher”; Define “Bona Fide”; Identify “De-identification” provisions in California and Federal law and harmonize.	Jun 2010 – Dec 2013
Identify “Public Health” provisions in California and Federal law and harmonize.	Feb 2010 – Jun 2011

Legal Committee Activity	Est. Timeframe
Identify “Patient Access” provisions in California and Federal law and harmonize.	Feb 2011 – Dec 2011
Identify “Marketing” provisions in California and Federal law and harmonize.	Feb 2011 – Dec 2011
Identify “Employer” provisions in California and Federal law and harmonize.	Feb 2011 – Dec 2011
Identify “Payment” provisions in California and Federal law and harmonize.	Jan 2012 – Aug 2012
Identify “Health Care Oversight” provisions in California and Federal law and harmonize.	Sep 2012 – Feb 2013
Identify “Required by Law” provisions in California and Federal law and harmonize.	Apr 2013 – Jul 2013
Identify “Law enforcement” provisions in California and Federal law and harmonize.	Jan 2014 – May 2014
Identify “Decedents/ Coroners” provisions in California and Federal law and harmonize.	Jan 2014 – May 2014
Identify “Government Functions” provisions in California and Federal law and harmonize.	May 2014 – Sep 2014
Identify “Judicial Administrative” provisions in California and Federal law and harmonize.	Jan 2015 – Apr 2015
Health and Safety Use / Purpose Limitation	Jan 2015 – Apr 2015
Identify “Worker’s Compensation” provisions in California and Federal law and harmonize.	May 2015 – Aug 2015
Identify “DIB/SSI Eligibility” provisions in California and Federal law and harmonize.	May 2015 – Aug 2015

9.3.3 Security Committee Activities

The Security Committee is responsible for identifying and recommending security policies to ensure the safeguarding of individual health information that is exchanged through California HIE services.

Security Committee Activity	Est. Timeframe
Security Baseline Assessment and Determination	Dec 3007 – Apr 2008
Access Control	Jan 2008 – Apr 2009
Develop Access Control Implementation Policy	Nov 2009 – On-Going
Develop Risk Management Implementation Policy	Mar 2010 – On-Going
Develop Consent Management Implementation Policy	Aug 2010 – On-Going
Develop Data Assurance Implementation Policy	Dec 2010 – On-Going
Develop Technical Controls Implementation Policy	Jun 2011 – On-Going
Develop Device and Media Implementation Policy	Dec 2011 – On-Going
Develop Security Incident Management Implementation Policy	Mar 2012 – On-Going
Develop Information Security Implementation Policy	Aug 2012 – On-Going
Develop Compliance Auditing Implementation Policy	Nov 2012 – On-Going
Develop Workforce Security Management Implementation Policy	Jan 2013 – On-Going
Develop Frequency of Actions Implementation Strategy Policy	Jun 2013 – On-Going
Develop Contingency Planning Implementation Policy	Dec 2013 – On-Going
Develop Facility Access Controls Implementation Policy	Jul 2014 – On-Going
Develop Network Security Management Implementation Policy	Dec 2014 – On-Going

9.3.4 HIE Committee Activities

The HIE Committee is responsible for taking the interim guidelines to the next level to recommend implementation strategies for privacy policies and security standards and work collaboratively with California's health information organizations to implement and test the requirements, resolve issues, and recommend refinement of the guidelines as necessary. This Committee was established in late 2009 and will be receiving completed proposals from the Privacy and Security Committees to develop implementation and best practices recommendations.

HIE Committee Activity	Est. Timeframe
Develop Implementation Strategy Tools	Mar 2010 – On-Going
Support Demonstration Projects	Mar 2010 – On-Going

9.3.5 Education Committee Activities

The Education Committee is responsible for the development of consumer and provider education resources and tools. The Education Committee will act as a resource and coordinate efforts with potential HITECH and ARRA funded demonstration projects, other demonstration projects and the Privacy and Security Guidelines by developing educational toolkits to include fact sheets, frequently asked questions, interactive website, consent forms, a library of educational resources, awareness materials (brochures), and Toll-Free Hotline number for consumers and providers. The Education Committee will also work with the Regional Extension Centers to provide information and outreach for providers.

The Education Committee's will gather feedback from entities in the community that utilize the toolkit. The toolkit will be refined over time to include this feedback from the community, where appropriate, as well as harmonize with any State and federal regulation or policy.

Education Committee Activity	Est. Timeframe
Standardize Opt-in Consent Form(s)	Jan 2010 – May 2010
Consumer Communications Toolkit	Jan 2010 – May 2010
Consumer Educational Fact Sheet	Jan 2010 – May 2010
Consumer FAQ's	Jan 2010 – May 2010
Consumer Brochures/Materials	Jan 2010 – May 2010
Consumer Interactive Website of Resources and Tools	May 2010 – On-going
Provider Communications Toolkit	Jan 2010 – May 2010
Provider Educational Fact Sheet	Jan 2010 – May 2010
Provider FAQ's	Jan 2010 – May 2010
Provider Brochures/Materials	Jan 2010 – Sept 2010
Test Consumer Communications Toolkit	Jun 2010 – Dec 2010
Test Provider Communications Toolkit	Sept 2010 – Apr 2010
Update Consumer Communications Toolkit	Jan 2011 – Apr 2011

Education Committee Activity	Est. Timeframe
Consumer Marketing/Outreach	May 2011 – On-going
Update Provider Communications Toolkit	Jan 2011 – Apr 2011
Provider Marketing/Outreach	May 2011 – On-going
Provider Interactive Website of Resources and Tools	May 2010 – On-going

9.4 Demonstration Projects

The overall goal is to create and maintain privacy and security rules that remove potential barriers and ensure equal access to all participants in California’s HIE. With such a divergent population of health care stakeholders with varying degrees of technical competency, each with different business requirements, it is not a simple task to level the field. Considerations must be given to technological feasibility, cost-effectiveness, business impact, and legal risk.

California’s tremendous diversity among health care stakeholders requires a close examination of implementation feasibility. To accommodate the diverse health care industry, which includes providers, health plans, hospitals, HIOs, and other entities, policies address the cost, technological capabilities, business impacts, and diligent timing of guideline implementation. The E-Health Branch will test preliminary privacy and security guidelines in organizations already deploying HIE and EHRs in California.

California is exploring specific demonstration projects to gauge health care stakeholders’ ability to implement privacy and security provisions related to HIE. The E-Health Branch is looking into several potential opportunities for testing privacy and security provisions including, but not limited to:

- Strategic Health IT Advanced Research Projects (SHARP) Program – ONC has announced the availability of \$60 million in funding for focused research in areas where breakthrough advances are needed to address barriers to the adoption of HIT to meet the goal of making EHRs available for all Americans by 2014. One of the four research focus areas is Security of HIT to address the challenges of developing security and risk mitigation policies and the technologies necessary to build and preserve the public trust as HIT systems become ubiquitous.
- Beacon Community Cooperative Grants – The U.S. Department of Health and Human Services (HHS) is dedicating a total of \$220 million in grants to support test cases for HIT and HIE within 15 communities. CHHS required that all California participants agree to participate in pilots. CalOHII’s likely partnership with participating entities will serve to test the various issues discussed below.

- *Regional Extension Centers* – The Regional Extension Program provides grants for the establishment of RECs to offer technical assistance, guidance and information on best practices to support and accelerate health care providers’ efforts to become meaningful users of EHRs. CalOHII’s Education and External Affairs Committee will provide education materials, tools, and resources to assist these RECs in California.
- *California Health Care Stakeholder Volunteers* – California is opening its demonstration projects to any willing participant who will test the policies and issues discussed below.

Several privacy and security demonstration projects are being proposed as meaningful tests that will advance California closer to standard privacy and security rules for HIE. The following list has been determined by the E-Health Policy Branch to represent significant issues that may be resolved through testing in demonstration projects.

- ***Consent – OPT IN*** – The “Opt In” consent option for health care entities electronically exchanging data will be tested in order to gather information regarding complexity, cost, business impact, and technological challenges that may prohibit health care entities from adopting the “Opt In” consent option.
- ***Consent – OPT IN with Restrictions*** – The “Opt In with Restrictions” consent option for health care entities electronically exchanging data will be tested as an alternative to the “Opt In” consent policy option.
- ***Consent Education for Patients*** – Consent education materials and tools will be tested to gather information related to the educational needs of a diverse population of people. This project will help take the pulse of Californian’s comprehension of HIE and will aid in further development of educational resources.
- ***Consent Training for Providers*** – Provider educational materials and tools will be tested to understand the provider community needs and acquire feedback regarding consent options and HIE challenges.
- ***Consent Registries*** – Health information organizations will test consent management services that allow consumers to drive consent while allowing providers to use the consent across multiple entities. The project will gather information regarding consent management cost, complexity, and business impact.

- ***Segregation of Data for Sensitive Health Information*** – The ability to sequester sensitive health information from other health information will be tested as a State and federal legal compliance effort. The project will gather information regarding cost, complexity, and business impacts.
- ***Two-Factor Authentication*** – Two-factor authentication for reliable access control will be tested for cost, complexity, and business impacts. Authentication is the process by which we determine that a system entry occurred by a specific individual and that individual carries the burden of proof that the access was not theirs.
- ***Authorization*** – Authorization is the process by which access is granted after requirements have been met. The variety of security authorization attributes for HIE requires a robust set of test scenarios. Attributes include data source, entity of requestor, role of requestor, use of data, sensitivity of data, and consent directives. This project will gather information regarding the various attributes, as well as the cost, complexity and business impacts.
- ***Patient Access*** – Testing patient access to their own health records will assist in understanding the technical challenges, as well as any business impacts or consumer navigation challenges.
- ***DURSA*** – The Data Use and Reciprocal Support Agreement (DURSA) is a comprehensive, multi-party trust agreement that will be signed by all NHIes both public and private, wishing to participate in the NHIN. California will test a DURSA that complies with California laws.

9.5 Contractual Framework for Enforcement

An essential element of a comprehensive and uniform Statewide policy framework for the exchange of health information is the foundation of trust that must exist between patients on the one hand and providers and users of data on the other, and among the providers and users of data themselves. California has concluded that the most effective way to establish this level of trust is to provide an opportunity for participants in HIE to have an open and transparent process for development of policy and to agree to adhere to the policies that result.

California has examined the experience of other States where adherence to common and uniform State policies has been sought to be enforced through the terms of grant agreements governing State funding provisions or as a condition of participation in the use of State resources such as technology platforms.

California has concluded that each of those models has deficiencies that can be initially addressed through a contractual model of participation and adherence.

In the contractual model, participants will be invited to participate in the Statewide collaboration process to develop legal, business, and technical rules that will govern health information exchange in California. The resulting agreement will require the HIE participants to adhere to the rules that are adopted through this process. A component of the contractual framework may be a DURSA so that each participant in HIE will know exactly the legal, business, and technical rules, including privacy and security guidelines to which each participant is bound.

The GE will ensure that appropriate oversight and enforcement mechanisms are established. Mechanisms include an arbitration forum in which disputes can be resolved, and authority to withdraw access to Statewide shared services for a non-conforming data requester, provider, or user.

10. Finance

This discussion of sustainability is as much a discussion of options as it is a plan for success. The State of California expects to meet the needs of its citizens through a combination of public and private investments in HIT and exchange. The State will engage in these activities by promoting coordination and collaboration among private and public entities, ensuring that privacy rights of individuals is protected, that the needs of the vulnerable and underserved are met, and providing funding and resources through the State HIE Cooperative Agreement program for activities that benefit all citizens in areas where a business case for a private entity is lacking.

10.1 Description of a Sustainability Model for California

There are many potential options for sustainability for the State HIE infrastructure. The State, either directly or indirectly in coordination with the GE, will sustain the HIE infrastructure using predictable revenues sufficient to support the planned operations, and generally not with short-term funds. The State plans to adopt a mixed delivery model providing most HIE services in a decentralized fashion, but with the support of centralized coordination and a centralized safety net.

Statewide sustainability models therefore will typically be geared away from direct support from institutions and providers and towards models that derive revenues from the broadest possible sources that derive value from such an infrastructure: public and private health plans (e.g. per member per month), current data providers (e.g., labs, radiology groups, hospitals); taxation models (including utility add-ons such as special land and cellular telephone line excises), or other broad based revenue sources.

Regional and local HIOs do not typically have access to taxation type models. Sustainability for HIOs that govern and operate the local HIE can be achieved in numerous ways. However, there is only one way that is not laden with risk: the HIO delivers value to its stakeholders while charging those stakeholders fees that are perceived by the stakeholder to be as much as or less than the value they perceive they derive from their participation in the HIO.

10.2 Current Modeling Approaches

Three strategic models for delivering reliable HIE throughout the State were considered. These models considered how much HIE might be sourced centrally versus how much would be sourced locally. The most central model budgeted for a large portion of HIE services to be provided by the State or GE. The decentralized model presumed very few services would be provided by the State or GE. The mixed model budgeted some funds to central services and some funds to local services. At this time, the State has selected the mixed model, however, more study is required to determine the ratio of funds distribution for

centralized versus decentralized services. Details of the models considered by the Finance workgroup can be found in Appendix 11.

10.3 Estimating Total Cost of HIE in California

The following analysis provides an upper bound cost estimate for total HIE coverage in California, based partially on work completed for the HIE Loan Fund Workgroup. To begin, we looked at expenditures for State-wide programs. New York has one of the more comprehensive programs of a State nearing the size of California.

State	Population	Area (Square Miles)
New York	19.3	54,000
California	36.5	164,000

To date, the State of New York has spent or committed \$492 million for HIE, including all the functions that HITECH provides with stimulus funds – training, regional extension centers, and assistance to HIOs. The State sees the expenditure to date as part of a billion dollar (\$1,000,000,000) project to implement HIE Statewide.

If California were to take the New York State budget and prorate it based on population, the budget for California would be \$1.89 billion. The investment made to date in New York indicates that the scope of what California must do to achieve linked records is a mammoth project, substantially beyond what the stimulus funds can begin to fund. Other States have committed State funds but not nearly on the level of New York, more as seed or organizational funding. Maryland has provided \$10 million. Florida has provided about \$5M so far in RHIO development and has estimated it will take another \$10-15M to accomplish an initial State health information network.²⁵

Smaller States have developed cost estimates for Statewide HIE as well. The State of Vermont began in October 2008 having each health insurer choose to pay 0.199% of all healthcare claims paid for its Vermont members in the prior year or a fee based on the insurer's proportion of overall claims in the prior year. This Health Care Information Technology Reinvestment Fee will produce approximately \$32 million over seven years. This fund will be used to support Statewide HIE and the adoption of certified Electronic Health Records (EHRs).²⁶ The population of Vermont is 621,270.²⁷ This is \$51.51 per capita.

²⁵ Laura Kolkman, Mosacia Partners, telephone conversation, July 1, 2009.

²⁶ State Level HIE, Advancing Effective State-level Approaches to Interoperability in the New Federal Context: Realizing State-level HIE Value and Sustainability, May 15, 2009, pp. 66-67. http://slhie.org/wp-content/uploads/2009/12/SLHIE_Brief_AdvancingEffectiveSLHIEApproachesFinalReleased5_27_09.pdf.

²⁷ US Census Bureau, 2008, <http://quickfacts.census.gov/qfd/States/50000.html>.

Assuming 50% is for EHR, the HIE per capita amount is \$25.76 for HIE. The California population is 36,757,000²⁸ so the California HIE budget for seven years would be \$947 million.

Local HIO leaders discuss expansion technically in terms of the cost per interface implemented. Laboratory interfaces are among the most complex. Local HIOs in California were asked about the average cost per interface, typically between a provider, the HIE and laboratories not yet connected to the HIE. The HIE leadership suggested an average of between \$15,000 to \$46,000 per interface (with the amount including both inbound and outbound interfaces) plus maintenance charges to the EHR system vendor selling the base interface and HIE staff support costs of about \$8,000 per year. OCHIN, a Pacific Coast provider of Epic systems primarily to community clinics and mental health programs, indicated that the average interface cost after implementing over 200 interfaces was as follows:

For a brand new interface (one direction)

Component	Cost	Explanation
Base interface	\$10,000 to \$15,000	Payment to vendor, one direction
Labor	\$15,000	OCHIN staff cost
Maintenance	18% of base interface cost	Annual recurring cost

For a secondary copy of the interface where OCHIN owns an existing interface (one direction)

Component	Cost	Explanation
Base interface	\$5,000 to \$10,000	Payment to vendor, one direction
Labor	\$5,000	OCHIN staff cost
Maintenance	18% of base interface cost	Annual recurring cost

According to these estimates, a first interface is \$25,000 to \$30,000 and a secondary copy of the interface is \$10,000 to \$15,000. Overall, OCHIN estimates the average cost per interface at \$20,000 one way. OCHIN has a highly skilled staff, has considered alternative approaches, and believes this is the real incremental cost for developing an additional interface and that **there are no economies of scale.**

The following are approximate counts of providers in California.

Organization Type	Count	Reference
HIE / RHIOs	20	Estimate
Hospitals	473	Office of Statewide Health Planning and Development ²⁹
Critical Access Hospitals	28	Office of Statewide Health Planning and Development ³⁰

²⁸ US Census Bureau, 2008, <http://quickfacts.census.gov/qfd/States/06000.html>.

²⁹ <http://www.oshpd.ca.gov/HID/Products/Listings.html>

Organization Type	Count	Reference
Medical Groups	291	Cattaneo & Stroud, Inc., List of Active Medical Groups ³¹
Solo & 2-Person Practices	14,837 (7,419 require interfaces; rest use ASP)	Medical Practice Business Blog ³²
Community Health Centers	110 centers, 796 sites	National Association of Community Health Centers, California Fact Sheet 2007 ³³
Rural Health Clinics	263	CMS ³⁴
Behavioral Health Providers	~1,200	US DHHS, Substance Abuse and Mental Health Services Administration ³⁵
Medical Laboratories	2,439	Manta ³⁶
Pharmacy Benefit Managers	50	Estimate based on contracting experience ³⁷
Total Interfaces Needed	12,105	
Physicians in CA (for information only)	45,651*	Kaiser Family Foundation
*Includes the solo & 2-person practices listed above.		

To make a crude estimate of interfaces, assume that there is one interface between each hospital, each critical access hospital, each medical group, each solo and 2-person practice, each mental health provider organization, each CHC and RHC and each medical laboratory. That totals 19,523 interfaces needed, assuming that every organization only interfaces with one HIO. While the lab interface is reasonably complex, the interfaces with provider organizations must transfer a number of different types of data: demographics, lab orders and lab results, radiology orders, referrals, chart notes, prescriptions, problem list, and CCD so there are actually a number of interfaces involved. It is reasonable to assume that smaller physician practices may elect to purchase EHRs through an application services provider (ASP) with the interfaces included, due to a lack of on site IT staff. This assumption reduced the number of interfaces needed to 12,105. To keep the numbers simple, a cost of \$40,000 was assigned to each interface (for both directions), including those that actually represent several interfaces but are counted only as one. The product is \$484 million. This estimate does not include the social capital cost of organizing HIOs, training, regional extension centers, hardware, networks, non-technical HIE staff, HIE management, base infrastructure, or any other HIE costs. Note also that this estimate does not involve the number of HIEs in any way. Whether there is one HIE or 50, the interface estimate is unchanged.

³⁰ <http://www.oshpd.ca.gov/RHPC/pdf/Ruralhospital/CriticalAccessHospitalsList061108.pdf>

³¹ http://www.cattaneostroud.com/med_group_reports/3-Web.pdf

³² <http://www.allbusiness.com/services/health-services-offices-clinics-doctors/4492452-1.html>

³³ <http://www.nachc.com/client/documents/research/2008-State-Fact-Sheets/CASStatefactsheet08.pdf>

³⁴ <http://www.cms.hhs.gov/MLNProducts/downloads/rhclistbyprovidername.pdf#page=120>

³⁵ <http://mentalhealth.samhsa.gov/databases/facility-search.aspx?State=CA&fullname=California>

³⁶ http://www.manta.com/mb_44_D0047_05/medical_laboratories/california. Somewhat mixed lab count.

³⁷ http://www.manta.com/mb_44_D0047_05/medical_laboratories/california. Somewhat mixed lab count.

Using the above estimates as crude indicators, the cost range for the project to provide HIE services throughout California is between \$1 billion and \$2 billion. The lower end of the range assumes costs beyond interfaces are another \$500 million or that the Vermont model applies. The higher end cost is comparable to New York State, prorated based on population.

10.4 Estimating Costs to Support RHIOs and local HIEs

Every HIO is different in the quantity of hospitals, reference labs and physicians it connects. However, there are rules of thumb on how much money one HIO will need to operate, including paying for the technology being used and maintained as well as the manpower to operate, market, and provide outreach. In general, a HIO can estimate its ongoing operating costs as the AVERAGE of:

- Quantity of full service hospitals in the catchment area multiplied by \$250,000/year
- Quantity of licensed health professionals in the catchment area multiplied by \$2,500/year
- Quantity of patients in the catchment area multiplied by \$2.50/year.

For example, a HIO with 10 full service hospitals, 1800 licensed health professionals, operating in a region with a population of 1.2 million people should expect an annual operating budget of:

$$((10*250000)+(1800*2500)+(1200000*2.5))/3 = \$3.33 \text{ Million/year.}$$

10.5 Upfront Financing Strategies and Sources

Each HIO will consider three main sources of upfront financing - grant funding, self-funding and capital markets funding. Grant funding will be pursued from federal ARRA activities, private sector foundations and endowments. It is best to maximize these dollars now and not expect that they will be available in the future.

Self-funding is likely to become the most attractive approach. The ROI on establishment of thin community health data services is increasingly attractive as health care moves massively from paper into electronic data services. The best example of self-funding is HealthBridge, an HIE in Cincinnati. In a recent CAeHC Webinar (10/22/09), Keith Hepp, Chief Financial Officer of HealthBridge, explained that HealthBridge was capitalized in 1997 with \$1.75 million in startup loans from two health plans and five health care delivery organizations. HealthBridge operates a light interface service (e.g., 97% of the network traffic is clinical results delivery) and does not seek to impose heavy transactional or hosting costs on users. Of note, HealthBridge does not charge physicians for access to the HIE, eliminating one potential barrier to widespread adoption. HealthBridge has been cash flow positive for 10 years. In

particular, Mr. Hepp recommended that HIEs, “Treat ARRA dollars the same as capital, and use ARRA money to buy-down future costs.”

The GE will also research and review the potential for funding from the capital markets. Various means such as venture capital, bank financing, and/or the bond market will be explored. The main prerequisite to secure funding from the capital markets will be a stable, ongoing revenue flow. However, there can be challenges to obtaining commercial capital, as shown by recent distress in the real estate and lending sectors; this type of funding requires reliable cash flow to pay it back. The Finance workgroup recognizes the current challenges to accessing the capital markets, yet also realize that this option must be considered as the budget and sustainability models are finalized. Having planned for this option will allow the GE, RECs and other entities to take advantage where possible and when this market becomes more viable than present conditions.

The ability to access banks, bond and venture capital will be dependent upon the stability and cash flow generated to repay debt in a sustainability model. Reserves will also be a critical consideration for analysis.

Bank financing may be available from both larger commercial banks and smaller community banks. Community banks in particular have programs available with the U.S. Small Business Administration and the Federal Home Loan Bank of San Francisco.

Other financing organizations could also provide package and secure bond financing; funding could require a minimum guarantee of loans through the RECs to all providers and HIOs. These commercial vehicles would be available to the State, the RECs and the HIOs directly, and the providers.

The RECs, with GE guidance, are responsible for identifying the funding models and pricing and repayment structures available to HIOs and providers. A referral list might be posted on the REC websites, and a process to evaluate the feasibility of offering packaged group financing would be initiated. The GE accounting staff will also develop a list of resources available to them for State HIE pricing, repayment and qualifications they must meet to determine viability for future needs. It is recommended that this exercise occurs during the sustainability model development to ensure that the model generates sufficient funding to qualify for financing and repay debt.

10.6 Funding Options

The Finance workgroup considered the following options for providing ongoing funding, apart from that received under the State HIE Cooperative Agreement program, to support the HIE.

- Taxes: a new State tax designated for the purpose of supporting HIE (would require two-thirds vote of the State legislature and) may be politically difficult; bond issuance; health plan claims surcharges; dedicated local or regional taxes.
- Access Charges and Subscription Fees: Possible fee structures would include a look-up charge, accessing patient data or results delivery or subscription fees based on the size and type of organization.
- Savings gain-sharing, or sharing with the HIE cost savings enabled by the exchange.

HIOs historically have had to achieve sustainability and survive without Statewide services, as these are a relatively recent phenomena (whereas there have been examples of sustainable HIEs since the mid 90s, such as the Santa Cruz HIE). They did so by providing valuable services to their key stakeholders, and found equitable fee or revenue structures for them. There are many stakeholders that potentially derive value from a regional HIE, including: Hospitals, Physician practices and groups, health plans, local and county public health departments, safety net clinics, FQHCs, jails, large employers, business coalitions, patients, and others.

The value derived from each entity above varies with the scope, breadth and focus of the HIE. In successful regional HIEs the breadth has or will increase until many or all of the potential stakeholders are deriving value. It is therefore imperative that the HIE can achieve and provide value to a few key stakeholders very early on, and leverage that success to draw in other stakeholders.

In regional HIEs, the typical primary stakeholders are hospitals and physicians. Several HIEs have found sustainability by simply providing hub-based connectivity solutions for these participants. In other words, reducing the expense to hospitals, reference labs and radiology centers for results delivery saves money which pays for a less expensive, more efficient shared infrastructure for all participating health data suppliers. Similarly, physician practices with EMRs require only a single connection and interface to the HIE versus interfaces to each of the stakeholders. The cost savings related to interface work on each side can more than pay for the HIE infrastructure, let alone the ongoing savings to the data sources in no longer producing paper, operating their own fax servers, paying for courier services, etc. HealthBridge in Greater Cincinnati excelled at this model, even taking over the paper printing and delivery for those not being delivered electronically. This “central print” model generates approximately \$0.18 profit for the exchange for every printed result, whereas each hospital saves approximately \$0.15 by having HealthBridge deliver it for them versus doing it themselves.

HIOs have been known to charge physicians an “HIE Connection” fee so as to aid in their sustainability. Physicians typically have less ability to afford technology expenses than hospitals, and therefore these fees tend to be low – in the range of \$10 to \$30 per month. However, in servicing large numbers of physicians, these fees can produce significant revenue sources for the HIO. If an HIE serving 600 physicians obtained \$15/month/physician, that HIE would be collecting \$108,000 per year from those physicians alone. However, it is notable that in the HealthBridge model, there is no physician fee.

Providing additional services (such as an EHR Lite) to physicians might significantly increase fees and generate additional revenues for the HIO. Prices for an interoperable, integrated clinical solution may be less than a typical cell phone bill. HIOs might profit by establishing volume license arrangements or hosting arrangements for these EHR or EHR Lite solutions. However, ASP model EHRs may have disadvantages that limit their broad adoption, so there is some risk to the HIO if a minimum volume is guaranteed to the EHR vendor. An HIO supplying an EHR Lite may be able to provide fee-based clinical analytics to simplify provider and community reporting for quality measures to CMS (for meaningful use incentives), public reporting, and to inform the community about where its healthcare is good, and where it needs to improve.

Physicians' fees may be absorbed by larger groups, such as IPAs, Medical Societies or other dues paying organizations, but ultimately those fees are paid by the individual physicians. If the fees are too high, there will be an internal power struggle which may lead to an unwillingness to continue to pay. HIOs can provide services to these organizations, which are often searching for ways to provide value to their membership. HMOs or other groups that contract with physicians to provide prepaid care for a set of patients often require specific health data communications connectivity between primary care, specialty physicians and institutional providers. The HMOs and like groups may pay additional fees to the HIO to enable that communications using their HIE.

The key to HIOs obtaining broader revenue streams is to be successful in the primary mission of connecting the physicians and achieving high adoption rates of HIE by them. Physician utilization of the HIE is the prerequisite to all other revenue models. If you do not have physician adoption, you do not have a sustainable HIE. Conversely, if you have high physician adoption rates, the opportunities for expanded participation and revenues is exponential. With high adoption rates, it is easy to attract the participation of public health, health plans and business coalitions. This advantage may be one of the reasons for the long term success of HealthBridge, maximally reducing barriers to physician participation.

Health Plan or payer participation can be a key formula to sustainability. In the past decade, payers have come to the conclusion that a successful HIE may save them significant money when the HIO can demonstrate that exchange is:

- Reducing duplicate test reimbursements;
- Reducing adverse medical events from drug interactions;
- Reducing ER visits for chronically ill patients;
- Providing a platform for medical home initiatives; and
- Facilitating data collection for data quality and Healthcare Effectiveness Data and Information Set (HEDIS) measurements.

The biggest hurdle, particularly in California, is the fragmentation of the commercial market. Payers are less willing to participate in an HIE if they feel they are subsidizing their competition. The next biggest hurdle for enticing payers to help fund the ongoing operations of the HIO is the data sharing agreement. Historically, physicians and payers have been at odds on use of clinical data: physicians do not want to be unfairly rated or paid less based on insurers having access to this data, yet insurance companies can often aid in preventative care through their care management outreach if they have real time access to clinical data. A balance must be struck and agreed to, and the amount of money a payer will be willing to spend will be commensurate with what they can save. Payers will realize cost savings from the reduction in excess tests and adverse events facilitated by health information exchange. However, HIOs must be willing to objectively analyze health care delivery in their communities to document this savings, even when a shared savings model is not the chosen revenue model. Payers may save significantly more money if, for example, they can routinely prevent ER visits by their diabetic patients due to timely receipt of salient clinical member data through HIE. Even more money can be saved by the payers if the providers are given clinical decision support advice at the point of service so they are following best practices or not overlooking key patient data. Each HIO will have to determine the balance they can achieve prior to approaching the payers with proposals for participation.

Local and county Public Health departments can provide ongoing funding to the HIOs for making services they already pay for more efficient. For example, HIOs can easily provide public health automated and semi-automated reportable events operations from hospitals and physicians, which can replace their existing inefficient and slow paper processes. Additionally, robust HIOs can provide

significant biosurveillance and disease outbreak information to public health, which public health can pay for through their current funding for the same services.

Providing the necessary funding for HIE and dividing costs up amongst stakeholders can be done in many ways. Some successful HIOs charge dues to their stakeholders, but apportion the costs commensurate with the ability to pay. For example, in an HIO where there is ample payer participation, the participation ratio may be something like: 40% payers + 35% hospitals + 25% physicians. This formula is overly simplistic. In CA, most care is not supplied on a percent of billed charges basis, which is the only fee structure to which the above formula might logically apply.

In most cases, HIOs have avoided transactional based fee models, but there are exceptions. HIOs have been wise in realizing that, for example, you do not want a physician to wonder whether it is worth 20 cents to view a lab test or a hospital lab to determine it is not worth sending out preliminary lab tests because they are charged by the test. Also, a payer will only pay where it is at risk for the payment. Examples, an insurance carrier won't pay for costs avoided by its ASO customers. An insurance company won't pay where the facility benefits (makes higher net profit) from avoided costs because it has undertaken less services to obtain its case rate. Many HIOs have preferred "all you can eat" models where participation fees are pre-ordained based on the size, type or ability of the organization to pay.

The most viable sustainable model for HIOs is to have broad based participation where stakeholders are charged fees or dues commensurate with the value they derive from the HIO combined with their ability to pay relative to other stakeholders. A complex model for access charges will be more complicated to manage than a simple one, and generally more costly to implement and maintain. However, it needs to be analyzed as to what structure, regardless of complexity, yields the most fair and acceptable result to participants.

The State will offer assistance to HIOs in determining which model or combination of model(s) is most likely to be effective in their region. The State will also assist all HIOs in the State by providing written support for those HIOs seeking to create improvement districts or other taxation authorities to raise needed funds from the local taxpayers, who ultimately benefit from effective HIE.

10.6.1 Approach to Developing a Sustainability Model

The following describes an eighteen-month Work Plan and activities to develop a sustainability model by quarter:

Quarter	Work Plan/Activities
1	<p>Hire one staff person with accounting and financial analysis skills to develop and extend budget models for full life cycle costing and manage daily accounting and reporting activities.</p> <p>Hire one staff person with skills to draft Statements of work, required project skills, procurement and contracting, and to hire and provide oversight and guidance to consultants, if needed. In addition to working with the financial staff to develop a sustainability model, support any governance-related procurements.</p> <p>These staff will work together with management and others (defined below) to develop surveys and RFIs. The objective is to collect information about and evaluate the various financial models currently in use for an ongoing revenue model to support costs that have been tested in the marketplace and are realistic. The objective is to identify those models that may be most effective for HIOs and models that best support State governance of HIE.</p>
2	<p>Staff will work with advisory groups, CalOHII and other State employees to:</p> <ol style="list-style-type: none"> 1. Develop a short survey that would list methods of payment or contribution by HIOs rated according to which is most to least desirable for the described HIE services; comments would be encouraged. The survey responses would be shared with HIE workgroups and known HIOs in the State. 2. Build on the CA Landscape inventory, possibly with a survey that updates and extends the survey work referenced in the Technical Architecture document. This would include identifying existing and potential new exchange networks that are developing partnerships that are considering becoming HIOs and their willingness to participate with HIE. 3. Develop a Request For Information (RFI) for HIE Core Services options. To encourage a broad range of options, the RFI should State that vendors are encouraged to respond with several solutions. These options might vary based on hosting environment and whether State owned and managed. Pricing for implementation and ongoing costs, such as maintenance and equipment upgrades should be included.
3	<p>The results of the payment / contribution survey responses would be totaled, comments grouped, results presented to management, working groups and HIOs, and next steps determined.</p> <p>The CA HIE Landscape would be updated to determine ongoing gaps. Options for filling HIE gaps would be developed. All potential resources would be considered, including: the CA Telehealth Network, Statewide Automated Welfare System (SAWS), DHCS Medi-Cal networks, tribal healthcare networks, and the DOD. The State would seek to collaborate before resolving to create or define HIE in a region with unmet need. Results will be shared with the HIE workgroups and HIOs in the State.</p> <p>Finally, results of the HIE RFI for Core Services would be consolidated and charted. If supported by the GE, project consultants will be hired to provide research on the pros and cons of each solution, with examples of State and local jurisdictions where each has been successful or failed, and identifying contributing factors. This might require interviews with representatives of those organizations. Results will be shared with the HIE workgroups and HIOs in the State.</p>

Quarter	Work Plan/Activities
4	<p>Staff may discuss with one or more workgroups, hold stakeholder meetings, or a preferred sustainability method for HIOs and the State may be self-evident. (HIOs will determine for themselves which sustainability model to use.) Staff would conduct outreach to identified healthcare organizations in regions lacking HIOs and HIE.</p> <p>Staff will review RFI results for Core Services and identify the solutions and pricing that passed the viability tests in Quarter 3. Staff will compare options, including evaluating costs to make recommendations to management. Recommendations will be shared with working groups and HIOs to ensure broad input. (This will reduce the chance that assumptions are inaccurate or that vendors have over-promised.)</p>
5	Staff will review and analyze the payment structures, develop budget models with this revenue information, and run models with the HIE cost information and governance costs. Staff will present options and cost models to management, the working groups, and HIOs for review and dissemination for Public Comment.
6	The sustainability model will be refined and finalized. Staff will continue to coordinate and support the expansion of HIE until there are either no gaps or the remaining gaps are inconsequential or cannot be covered.

10.6.2 Budget Narrative (Cost Estimates, Staffing Plans, Schedule of Tasks)

The State will have several axes on which to ensure effective HIE in California. Each of these axes requires a portion of the State budget for HIE in order to ensure that it is supported effectively. The numbers provided in the following sections reflect those submitted to the Office of the National Coordinator as of February 1, 2010. These are provided as directional input but will be significantly modified throughout the Operational Planning process. More narrative will be added as the line items are adjusted to reflect the selected model and associated technical architecture.

10.6.3 Governance Entity Cost Estimates

The budget for the GE will need to support staffing and resources. For years one through four:

Cost	2010	2011	2012	2013	Total
GE Staff	\$1,500,000	\$1,500,000	\$1,000,000	\$750,000	\$4,750,000
GE Benefit	\$450,000	\$450,000	\$300,000	\$225,000	\$1,425,000
State staff for Privacy and Security, Governance, Etc.	\$534,456	\$534,456	\$534,456	\$534,456	\$2,137,824
State Benefits	\$180,678	\$180,678	\$180,678	\$180,678	\$722,712
GE Travel	\$98,333	\$98,333	\$98,333	\$60,833	\$355,832
State Travel	\$20,334	\$20,334	\$20,334	\$20,334	\$81,336
GE Supplies	\$105,750	\$22,250	\$27,750	\$23,500	\$179,250
State Supplies	\$64,500	\$20,050	\$17,500	\$17,500	\$119,550
Contract positions (legal, recruiter, consultant, etc)	\$1,106,500	\$642,000	\$496,500	\$484,000	\$2,729,000
Facilities and Other	\$165,248	\$162,748	\$127,704	\$109,438	\$565,137
Governance Total:	\$4,225,799	\$3,630,849	\$2,803,255	\$2,405,739	\$13,065,641

10.6.4 Patient Engagement Cost Estimates

The budget for Patient Engagement will need to support outreach activities. For detail on the activities of the Patient Engagement workgroup, see section 6, Patient Engagement in HIE. The cost estimates for the activities detailed therein follow.

Cost	2010	2011	2012	2013	Total
Contractual \$210,000 for engagement of a consumer relations firm to survey the population, design the campaign, and detail out the communication methodologies	\$200,000				\$200,000
Full-time project manager with administrative and budget management support to manage the efforts, reporting to GE.		\$77,300	\$77,300	\$77,300	\$231,900
Materials: mailings, web campaigns, road shows, social media, meetings, etc to implement Communications Campaign as specified by consumer relations firm.	\$100,000	\$100,000	\$75,050	\$75,050	\$350,100
Discretionary: meetings and outreach to “influencers”, key provider, community, and patient organizers who can become champions for HIE engagement.	\$4500	\$4500	\$4500	\$4500	\$18,000
Patient Engagement Total:	\$304,500	\$181,800	\$156,850	\$156,850	\$800,000

10.6.5 Provider Engagement Cost Estimates

The budget for Provider Engagement will need to support outreach activities. It is possible that this will become a line item in the GE budget. The staff and resources to meet this need will be the same as those for patient engagement and included in the budget outlined in 8.2.2.

10.6.6 Underserved and Vulnerable Populations Cost Estimates

The budget for these populations will need to support both outreach and data collection. The outreach efforts will need to address the populations identified as well as providers to and decision makers for those populations. Data will need to be collected at baseline and periodically, perhaps annually, in order to assess the penetration and effectiveness of HIE. Estimated budget:

Cost	2010	2011	2012	2013	Total
Materials: mailings, web campaigns, road shows, social media, meetings, etc to implement Communications Campaign as specified by consumer relations firm.	\$70,000	\$70,000	\$70,000	\$70,000	\$280,000
Discretionary: meetings and outreach to “influencers”, key provider, community, and patient organizers who can become champions for HIE engagement.	\$5000	\$5000	\$5000	\$5000	\$20,000
Underserved and Vulnerable Total:	\$75,000	\$75,000	\$75,000	\$75,000	\$300,000

10.6.7 Technical Services

The budget for technical services will need to include initial capital costs, fixed operating costs, and variable operating costs. Because the technical processes should be running online, it is possible that cloud computing options offer zero capital costs, minimal fixed operating costs, and variable costs which are then proportionate to the services provided. In this way, the revenue received for offering these services should offset the costs. For years one and two:

Cost	2010	2011	2012	2013	Total
Equipment	\$200,000	\$100,000			\$300,000
Contracts for State level core services	\$4,000,000	\$2,000,000			\$6,000,000
Contracts to connect immunization registries	\$500,000	\$500,000			\$1,000,000
Contract to expand HIE footprint	\$5,000,000	\$3,000,000			\$8,000,000
Contract to connect existing HIOs	\$3,000,000	\$2,000,000			\$5,000,000
Technical Services Total:	\$12,700,000	\$7,600,000	\$-	\$-	\$20,300,000

10.6.8 Evaluation

In order to assess the effectiveness of the GE, HIE services Statewide, and each of the components individually mentioned above, there will be resources allocated to baseline and ongoing measurements and metrics. Determination of which metrics to use shall be completed in year one. For years one through four:

Cost	2010	2011	2012	2013	Total
Evaluation Contract	\$350,000	\$175,000	\$125,000	\$126,000	\$776,000
Audit	\$75,000	\$75,000	\$75,000	\$75,000	\$300,000
Specific staff in GE					
Technical Services Total:	\$425,000	\$250,000	\$200,000	\$201,000	\$1,076,000

10.7 Issue Resolution and Risk Mitigation

This section reviews issues and risk mitigation strategies relevant to all workgroups.

Risk	Mitigation Strategies
Patients do not participate/interact with the HIE including recording their preferences, authorizing use, etc.	Patient criteria for success and metrics may be overly generalized, and should reflect the health status and accessibility of the target population on a segment by segment basis.
Vendors of Consumer systems (e.g. EMR, PHR, EHR [.5] , Care Management Applications, etc.) do not comply with integration and data sharing requirements of the HIE creating islands of PHI that are neither readily available to patients, or available for comprehensive health view of the patient, or available to be managed through master preferences and authorizations registered by patients in the HIE.	1.) Medi-Cal reimbursement contingent upon HIE participation and openness. 2.) Some sort of Patient available identifier that clearly demonstrates the HIE compatibility and inclusion of PHI or other Health Information.
Hospitals and providers adopt systems that are incompatible with HIE systems, and therefore not be available for patient interactions through the HIE.	1.) Medi-Cal reimbursement contingent upon HIE participation and openness. 2.) Identifying the HIE compliance (read, write, read/write) of a Provider / Physician / Group.
Labs, pharmacies, ancillary providers, and other entities do not preserve downstream data preferences of consumers.	The GE will obligate all participants in HIE to observe privacy, security, and data preferences of consumers through contractual agreements with enumerated remediation.
If subscription or access fees may be prohibitive for some providers or consumers to access HIE services.	The GE will determine a policy for grant assistance to enable universal access to the HIE.
Security of consumer equipment (personal computers, cellphones, etc) in case of loss.	Identity verification on device required and/or ability to delete data remotely.
False positives or false negative matches of patient and data.	1) All incoming data is linked to originating data source, patient, and care giver leaving a detailed provenance to resolve the mis-matching of data. 2) Allow consumers to verify and correct data.

Risk	Mitigation Strategies
Not all remote monitoring devices have the ability to be networked	An explicit provision in GE contractual agreements that clarifies that the hand entry of biometric readings into HIE connected applications and systems satisfies this requirement is needed.
Data integrity for vulnerable and underserved populations. (Example: many services provided to managed care members are carved out from managed care and provided through fee for service Medi-Cal.)	Real-time linking of data from behavioral health, dental, Adult Day Healthcare, In Home Supportive Services, and CCS is critical to comprehensively manage patients.
The Behavioral Health population is migratory and multiple (and distinct) registration information profiles exist simultaneously in multiple databases.	Create data-stamping standards for creating patient profiles and notifications to other providers to cross-reference and combine multiple profiles for the same patient.
Fraud and abuse of HIE services.	The GE will maintain a strong fraud and abuse policy that is referenced explicitly in all contractual agreements, with penalties for noncompliance.
Breach of protected data, violation of privacy standards, unauthorized disclosure of PHI.	Working with CalOHII and CalPSAB, the GE will develop a plan for a potential breach of information and factor into its budget the costs of disclosure expenses related to customer contact and public response.
A local HIO or RHIO has a data breach.	The GE can provide consulting help and remediation expenses such as technology and training. The GE may also want to consider an oversight/audit role for ensuring that the basic legal and operational processes are in place to deal with disclosure and breaches of information by the HIO.
Physicians may not adopt systems that are compatible with HIE systems, and therefore not be available for patient interactions through the CA State HIE	1.) Medi-Cal reimbursement contingent upon HIE participation and openness. 2.) Identifying the HIE compliance (read, write, read/write) of a Provider / Physician / Group.

10.8 Finance Controls and Reporting

10.8.1 Readiness Requirements for Receipt of Federal Stimulus Funds

On March 27, 2009, the Governor's Executive Order S-02-09 created the California Recovery Task Force to take the lead responsibility for establishing a systematic method for collecting, creating reporting standards, and centrally locating all information regarding the uses, status, outcomes, and accountability of ARRA funds received by California.

As such, all State agencies receiving ARRA funds will be responsible for ensuring the necessary systems are in place to provide proper oversight, accounting, reporting, and project management controls to ensure all ARRA funds are used efficiently and for the intended purposes.

Readiness Factors

As requested by the California Recovery Task Force, the Department of Finance, Office of State Audits and Evaluations (OSAE), recently reviewed six State agencies' readiness to receive and administer ARRA funds, with specific emphasis on their accountability and oversight processes. Based on these reviews and guidance contained in the ARRA, the following core readiness areas have been identified as essential to ensure adequate oversight related to ARRA funding:

1. Oversight and Fraud Prevention

- Agencies are to perform an ARRA-related risk assessment in order to identify and mitigate potential risks.
- Agencies are to provide fraud awareness training to its' employees and its recipients to make them aware of potential vulnerabilities of ARRA funds to fraudulent use.

2. Grants Management and Accountability

- Agencies are to provide training to recipients regarding proper grant management and accountability.
- Agencies are to develop standard grant templates with specific ARRA language and written guidance for recipients.
- Agencies are to develop tracking mechanisms for specific ARRA data elements, including number of jobs created.

3. Reporting Requirements

- Agencies must be prepared to separately track the receipt and disbursement of ARRA funds in their accounting systems.
- Agencies must develop and maintain systems to track and identify administrative costs associated with administering ARRA funds.

4. Transparency

- Agencies are to develop clear and informative information reporting systems.

Each State agency receiving ARRA funds must review and at a minimum implement the above readiness factors prior to the receipt and disbursement of funds.

Recent Readiness Review Concerns

The recent reviews of six State agencies' readiness to receive and administer ARRA funds identified the following concerns:

1. Departments found that additional federal requirements for existing programs are creating unanticipated challenges.
2. There is an increased need to improve oversight and controls by identifying and mitigating departmental risks related to ARRA on an ongoing basis.
3. There is a need to identify high-risk sub-recipients for additional training and monitoring.
4. Agreement language must be developed requiring grantees to comply with changing ARRA requirements.
5. Statewide standards for the form and content of reporting ARRA information must be developed and communicated.
6. A Statewide plan to coordinate and communicate data collection efforts among the various ARRA funded departments must be developed and communicated.
7. Departments expressed the need to coordinate all audit efforts to prevent or minimize duplication.

It is recommended that all departments continue coordination efforts with State and federal authorities to obtain clear guidance over allowable administrative and overhead expenses, oversight roles and responsibilities for direct funding to localities, if applicable, and additional ARRA specific reporting data requirements.

Potential Risks of Federal Audit Exceptions

The readiness reviews and the guidance provided in this bulletin are intended to assist State agencies in identifying areas of potential risk, and affording agencies the opportunity to take the necessary corrective actions to mitigate identified risks in order to ensure compliance with all federal requirements.

Failure to comply with ARRA requirements may result in potential federal audit exceptions and the repayment of federal funds, with a potential negative impact on State general fund.

Additional Readiness Reviews

Additional agency/department reviews will be performed to assess readiness. Upon completion of readiness reviews, agencies/departments must submit a Corrective Action Plan (CAP) to address any concerns identified. CAPs are to be submitted electronically directly to OSAE within 30 days of notice. CAPs are to be submitted to: RecoveryAct.OSAE@dof.ca.gov

Each agency or department will be contacted in the near future to schedule a readiness review.

Guidance and Future Bulletins

As previously Stated, the above general guidelines and instructions are intended to assist agencies/departments in complying with ARRA requirements to ensure proper accountability and reporting. The above guidance is not all encompassing as federal requirements continue to evolve.

10.8.2 Accounting Requirements for Recovery Act Funds

Directive: Departments who have or will receive ARRA funds must follow the procedures outlined below and work with the SCO to establish unique Federal Trust Fund account codes.

Pursuant to OMB Circular A-133, Subpart C, Section .310, all auditees are required to prepare a Schedule of Expenditures of Federal Awards (SEFA). Because of limitations in its automated accounting system, the State is unable to provide the required SEFA. Instead, the Department of Finance, Office of State Audits and Evaluations (OSAE), prepares a Schedule of Federal Assistance (Schedule), which shows total

cash receipts, rather than expenditures by program. The Bureau of State Audits uses this Schedule to determine which federal programs are major programs for single audit purposes.

For fiscal year 2008-09, the OMB is requiring States to report ARRA expenditures separately in the SEFA. As noted above, for single audit purposes, the State will be reporting total receipts, rather than expenditures. OSAE utilizes the State Controller's Office (SCO) Federal Trust Fund Report (also known as Report 50) to capture all federal receipts for the fiscal period. However, for fiscal year 2008-09, the ARRA receipts were not reported separately to SCO by State departments.

As a result, on August 5, 2009, OSAE requested all State departments provide all ARRA receipts (on a cash basis). State departments should report cash received as a recipient, which is defined as a non-federal entity that expends federal awards received directly from a federal awarding agency to carry out a federal program. This request was made via email and was due August 18, 2009. For future fiscal years, it is anticipated the SCO's Report 50 will be able to capture the required federal receipts with ARRA receipts segregated.

Please note: This request for ARRA receipts (cash basis) is not related to the ARRA reporting requirements per Section 1512.

In order to ensure ARRA receipts are tracked separately from other Federal awards and to facilitate development of the Schedule for fiscal year 2009-10, the SCO is capturing ARRA receipts by establishing unique Federal Trust Fund account codes. ARRA accounts are designated a "6" series in the project number (P/N) field. This enables SCO to track the receipt of ARRA funds separately from other federal funds.

The SCO is designating a "6" series in the P/N field on ARRA accounts that were previously established without the "6" series P/N number and notifying agencies via memo of the new account coding. In these cases, the SCO is reclassifying the receipts to the amended ARRA account.

If a department previously submitted a Request to Establish or Amend Federal Trust Fund Account (AUD 10a) for ARRA funds without including any indication that the federal program is ARRA related, the department must inform the SCO of the account code so the SCO can validate the federal program has been set up as an ARRA account.

For departments that did not establish an ARRA account, but used an existing account for ARRA money, an AUD 10a form must be submitted to the SCO to request an ARRA specific account. Departments will be notified by memo after the SCO establishes the ARRA account. Upon receipt of the memo,

departments must submit a Controller's Receipt (CR) correction to reclassify receipts to the new ARRA account.

Instructions specific to establishing an ARRA Federal Trust Fund account are as follows (see highlighted areas on attached sample form):

- Account Title: Include "ARRA" at the end of the account title
- Federal Program Name: The Federal program listed in the Catalog of Federal Domestic Assistance (CFDA). The program name should correspond to the Federal Catalog Number (FCN) in Box 3A of the AUD 10a form. This is a five digit number used by the Federal Government to identify its various programs.
- P/N: The SCO is using this field as an identifier for ARRA funds. A "6" series P/N code is assigned by the SCO.

The department should use the ARRA specific Federal Trust Fund account code on all accounting transactions related to ARRA funds. The AUD 10a form is available on the SCO website at: http://www.sco.ca.gov/Files-ARD/State_aud10a.pdf. Completed forms are sent to the SCO, Division of Accounting and Reporting, for approval.

In addition to SCO's efforts to establish unique FCNs to track the receipt of ARRA funds, departments are reminded that both receipts and expenditures need to be tracked separately for ARRA funds in departmental accounting systems.

For departments using the California State Accounting and Reporting System (CALSTARS) and receiving ARRA funds, this may require the establishment of the Federal Catalog/SCO Project Number in the Federal Catalog Descriptor (D40) Table, a Project in the Project Descriptor (D42) Table, a Project/Work Phase in the Project Control (PC) Table (which references the D40 and D42 Tables), and a Program Cost Account (PCA) in the Program Cost Account Table (which references the PC Table). In cases where a department has already charged both non-ARRA funds and ARRA funds to one Federal Catalog/SCO Project number, the ARRA funds may need to be separated through adjusting entries. For more information about the Federal Trust Fund Accounting in CALSTARS, please refer to the CALSTARS Procedures Manual Volume 3, Chapter 10 which is available on the CALSTARS website: <http://www.dof.ca.gov/html/calstars/calsdocs/manual/VOLUME-3/v3ch10.pdf>.

Departments who are not on CALSTARS should also ensure that they are adequately tracking both receipts and expenditures for ARRA funds. Adequate accounting controls shall be established to ensure that ARRA funds are accurately reflected in the accounting systems. Departments should establish monthly reviews and reconciliations of ARRA receipts and expenditures.

Departments are also reminded that they are required to submit data necessary to comply with Section 1512 of the ARRA by using the California ARRA and Accountability Tool (CAAT). It is important that departments maintain accounting records to support information submitted to CAAT.

Please see Recovery Act Bulletins 09-12 and 09-13 for additional information on ARRA reporting. Recovery Act Bulletins are available on California's Economic Recovery portal at:
<http://www.recovery.ca.gov/HTML/About/supportingdocuments.shtml>.

If you have any general questions, please contact the Fiscal Systems and Consulting Unit hotline at (916) 324-0385 or e-mail: fscuhotline@dof.ca.gov. For questions about AUD 10a or CR processing, please contact your SCO accounting analyst.

10.8.3 The California ARRA and Accountability Tool (CAAT)

The California ARRA and Accountability Tool (CAAT) was developed as an on-line data filing tool, allowing California State Departments receiving ARRA funds to provide required data about the funds received and disbursed. Departments have principal responsibility for the quality of the information provided, including the information provided by Subrecipients. As Stated in OMB Memorandum M-09-21:

Data quality is an important responsibility of key stakeholders identified in the Recovery Act. Prime recipients, as owners of the data submitted, have the principal responsibility for the quality of the information submitted.

Consequently, Departments (Prime recipients) are responsible for directing their Subrecipient organizations to provide CA-ARRA data in accordance with the schedule previously referenced, and for validating the quality of data submitted. In addition, only the individuals authorized by the Director or other entitled head of their organization can approve CA-ARRA Department and Subrecipient data for inclusion in State and federal reports.

As Stated in RAB 09-12, California is a centralized reporting State for ARRA. As such, all State Department data will be collected and submitted through the CAAT. Therefore, Departments must NOT register at FederalReporting.com as suggested by Recovery.gov. ALL Departmental reporting will be

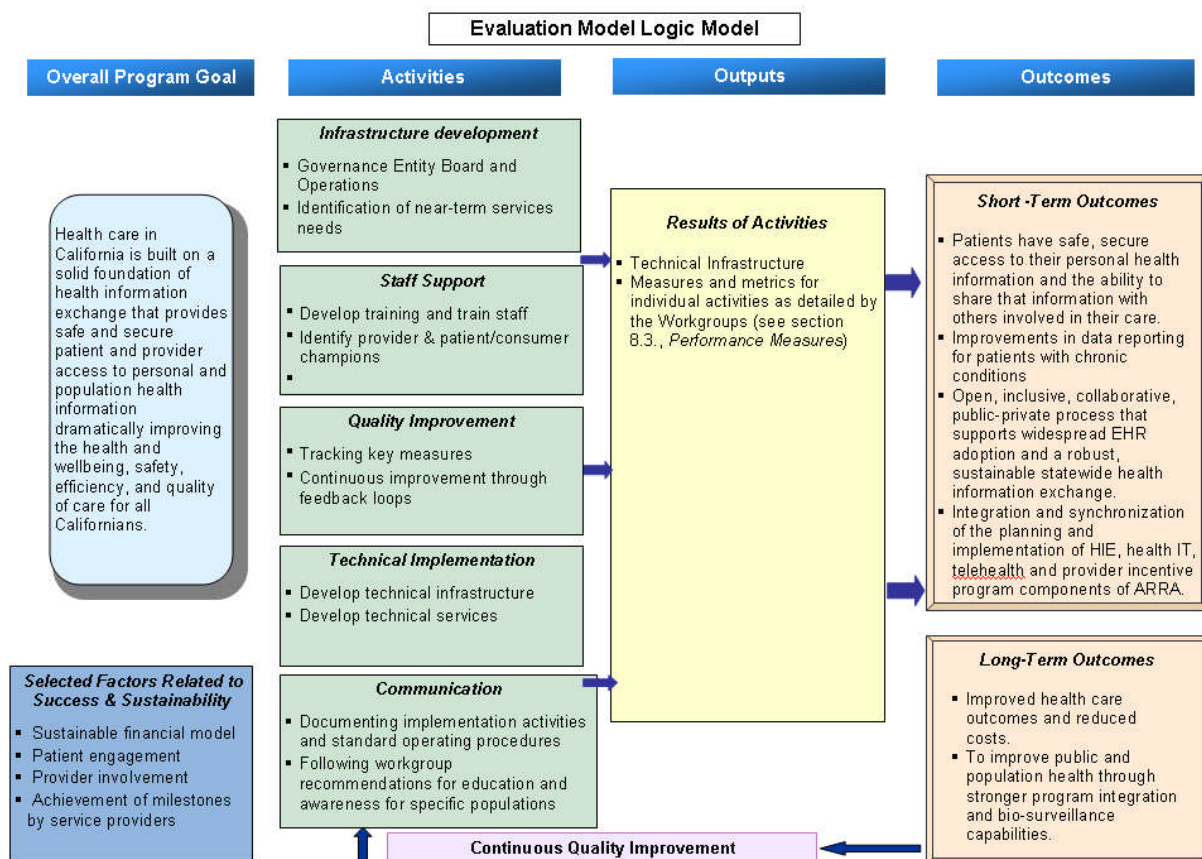
done through the CAAT. Departments should also inform their Subrecipients not to register at FederalReporting.gov. All Subrecipient data will be collected through the CAAT as part of the Departments' CA-ARRA data submission.

11. Evaluation

11.1 Framework

Achieving HIE goals is a systems-focused effort, involving multiple stakeholders, and incremental processes. Additional work needs to be done to define the measures and mechanisms that will be used to assess the near term effects and systemic impact of HIE development efforts. ARRA highlights the importance of supporting health care system improvements, such as promoting care coordination and improving public health.

California is dedicated to demonstrating that progress is made toward these ends by employing a robust evaluation program. The goal of the evaluation effort is to demonstrate the economic and quality value of health IT investments and the effects of investments on providers and consumers, determine what is working and what needs to be improved, disseminate these lessons learned broadly within the State as well as at a regional and national level, and iteratively refine health IT in the State. To evaluate outcomes, the State, the GE, and selected Evaluator will use a model developed by the California Health Care Foundation:



11.2 Process

The State and the GE work together to define the details of the evaluation process, and will work collaboratively to provide oversight and guidance to the independent evaluator. In addition, California will leverage technical assistance offered from the federal government. At a minimum, the evaluation process will include:

- Continuous evaluation, reassessment and revision of the State strategic and operational plans.
- An annual evaluation that will be coordinated with the national program evaluation.
- Reporting requirements specified in the State HIE Cooperative Agreement program plus additional reporting requirements identified during the development of the operational plan.
- Performance metrics specified in the State HIE Cooperative Agreement program plus additional performance metrics identified during the development of the operational plan.
- Coordination with national program evaluation and leverage technical assistance from the federal government for the California evaluation in an effort to implement lessons learned that will ensure appropriate and secure HIE resulting in improvement in quality and efficiency.

11.2.1 Procurement and Budget for Evaluator

California will allocate a portion of the funding received through the State HIE Cooperative Agreement Program to an independent evaluation process. Likewise, as the long-term funding model is defined, it will include a mechanism to fund on-going evaluation and analysis.

From March – June 2010, the GE will draft procurement requirements, review with the eHealth Advisory Board and for legal compliance, and revise. The draft RFP for the Evaluator will be sent for Board and Legal review in February, and released by the end of that month. Responses are due by the end of April, with the contract awarded by the end of June 2010.

11.2.2 Reporting and Evaluation Cycles

The GE will oversee a series of four evaluation cycles. The first Evaluation period is a “mini-period,” with three phases occurring each per month: Data Collection in July; Data Analysis in August; and Evaluation Reporting in September 2010.

The second evaluation period begins with a 2-week period of refining the evaluation criteria based on the reporting from the inaugural cycle; but then proceeding through the same three phases; with the entire evaluation period lasting one year (from October 2010 through September 2011.) The third evaluation period begins immediately following, in October 2012, lasting one year (through September 2012.) The fourth evaluation period follows the same pattern of four phases, lasting from October 2012 through September 2013.

11.3 Performance Measures

Performance measurement is a critical element of continual improvement. As such, the measures will necessarily evolve over time, and efforts will be refocused on areas of need. This initial set of measures is intended to establish State-specific and national perspectives on the degree of provider participation in HIE enabled State level technical services.

Specific reporting requirements required by the State HIE Cooperative Agreement program are included below.

- Has the organization developed and implemented financial policies and procedures consistent with State and federal requirements?
- Does organization receive revenue from both public and private organizations?
- What proportion of the sources of funding to advance HIE are obtained from federal assistance, State assistance, other charitable contributions, and revenue from HIE services?
- Of other charitable contributions listed above, what proportion and dollar amounts of funding comes from health care providers, employers, health plans, and others (please specify)?
- Has the organization developed a business plan that includes a financial sustainability plan?
- Does the governance organization review the budget with the oversight board on a quarterly basis?
- Does the recipient comply with the Single Audit requirements of OMB?
- Is there a secure revenue stream to support sustainable business operations throughout and beyond the performance period? If so, how long will the sustainable revenue stream last?

During the operational planning process, each of the public workgroups developed performance measures to evaluate achievement of objectives above and beyond what is required by the ONC guidance. A description of those measures follows.

11.3.1 Patient Engagement Performance Measures

To address performance measures for Patient Engagement, a Metrics and Measurement subcommittee of the Patient Engagement workgroup convened with the objectives of developing a common set of metrics that cross all populations with follow up development of incremental metrics that may be useful for unique populations

The metrics subcommittee included recommendations that support the adherence to metrics; e.g., a recommendation that providers be reimbursed. Metrics adopted will measure the percentage of the population interacting with the system, with the understanding that patient engagement is divorced from enforcement and outcomes.

The Metrics sub classifications will comprise 4 layers:

- Infrastructure growth as measured by rate of adoption;
- Effectiveness and efficiency of process;
- Data Availability and accessibility; and
- Quality of data and response times.

The Metrics subgroup will meet twice per week during the metrics development process, and use the following proposed framework to develop specific metrics and measurement for engaging consumers with HIE:

The Metrics subgroup developed the following metrics worksheet to measure the achievement of a functional, effective HIE:

MU Goals and Goals/Objectives (What law says we have to have in place to meet criteria)	Electronic prescribing and refill requests including sharing med lists with patient	Clinical laboratory ordering and results delivery	Clinical summary exchange for care coordination and patient engagement	Recommend tools to ensure that patients have access/control of their health information
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Consumer / Patient measurements of success “how do we know it worked”?	(1) Patient is able to request refills online, and (2) EP is able to respond and communicate with the pharmacy	(1) Lab results are available to patient within 48 hour period of time (or sooner). (2) Patient can link to information related to lab results (relevant ranges, etc.)	(1) Summary information is available to patient (2) Patient has been provided adequate instruction on appropriate action based on information provided.	Patient provided with various options for obtaining information, depending on technical know-how and accessibility to electronic media.
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Effective Year: 2011

Requirement/Objective: Engage patients and families in their Healthcare

Target (Definition): Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request.

Metrics					
Capability	Adoption	Utilization	Effectiveness	Barriers	Recommendations
Capability: Provide patient with any requested materials such as lab test results, blood work results, etc.	1) # patients aware of availability of information 2) % of providers with capability	1) % of patients and/or their representative electronically requesting information or requesting electronic information. 2) % distribution to patients.	1) % Patient’s subsequent re-use of the capability. 2) # / % patients responding to information pushed to them.	1) Small patient population with personal internet access. 2) Issues with multiple users, elderly patients. Consider patient and/or their representative (proxy).	This should be part of training and education of patients. It should be identified as operational and material savings for covered entities.
<i>Data Source:</i>	<i>(1) Self-reporting by physician office.</i>	<i>Physician records / EMR / PHR</i>	<i>E-mail, web page</i>		
<i>Form of Metric (data structure):</i>	<i>1) # patients aware of availability / total # of patients. 2) # providers with capability/total providers</i>	<i>1) # patients requesting info / total # of patients. 2) # patients receiving information / # patients with requests</i>	<i>Returned (bad) e-mails / # notified</i>		
<i>Frequency of Reporting</i>	<i>Quarterly or Annually.</i>	<i>Frequency of report reporting.</i>	<i>Ad hoc</i>		

Effective Year: 2011

Requirement / Objective: Engage patients and families in their Healthcare

Target (Definition): Provide patients with timely electronic copy of their discharge instructions and procedures at time of discharge. (does not include inter-facility transfers)

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
Capability: Provide patient with discharge instructions indicating that lab and other results will be available within 96 hours.	% of hospitals or EPs who have the capability.	% of discharge orders delivered electronically.	Quality, self-management, readmits. (TBD). Verified receipt and understanding of materials.	Small patient population with personal internet access.	This should be part of training and education of patients. It should be identified as operational and material savings for covered entities.
<i>Data Source:</i>	<i>Self-reporting by hospital or physician office.</i>	<i>EMR.</i>	<i>E-mail, web page</i>		
<i>Form of Metric (data structure):</i>	<i># patients aware of availability / total # of patients.</i>	<i># of results delivered electronically / total # of results (per patient)</i>	<i>Returned (bad) e-mails / # notified</i>		
<i>Frequency of Reporting</i>	<i>Quarterly or Annually.</i>	<i>As requested.</i>	<i>Ad hoc</i>		

Effective Year: 2011

Requirement / Objective: Engage patients and families in their Healthcare

Target (Definition): Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP.

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
Capability: Provide patient with instructions indicating that lab and other results will be available within 96 hours.	% of hospitals or EPs who have the capability.	% of discharge orders delivered electronically.	% of patients who follow up with next steps and recommended treatment	Small patient population with personal internet access.	This should be part of training and education of patients. It should be identified as operational and material savings for covered entities.
<i>Data Source:</i>	<i>Hospital self reporting</i>	<i>EHR database records</i>	<i>EHR/PHR</i>		
<i>Form of Metric (data structure):</i>	<i># hospitals with capability / total # of hospitals or EPs counted.</i>	<i># pieces of information available online / volume of information (# of pieces of information)</i>	<i># patients acting on recommendation / # of patients requiring follow up</i>		
<i>Frequency of Reporting</i>	<i>Quarterly or Annually.</i>	<i>Ongoing.</i>	<i>Ad hoc</i>		

Effective Year: 2011

Requirement / Objective: Engage patients and families in their Healthcare

Target (Definition): Provide clinical summaries for patients for each encounter.

Metrics					
Capability	Adoption	Utilization	Effectiveness	Barriers	Recommendations
Capability: Provide patient with a clinical summary at conclusion of each encounter. Clinical summary to include findings, recommendations and next steps.	% of hospitals or EPs who have the capability.	Written summary at conclusion of visit with detailed summary available via electronic query	% of patients who follow up with next steps and recommended treatment	Duplicative to provide patient with written summary to “take” with them.	
<i>Data Source:</i>	<i>Hospital self reporting</i>	<i>EHR database records</i>	<i>EHR/PHR</i>		
<i>Form of Metric (data structure):</i>	<i># hospitals with capability / total # of hospitals or EPs counted.</i>	<i># clinical summaries available electronically / # clinical encounters for any given patient.</i>	<i>Experience Stated as unsatisfactory by patient.</i>		
<i>Frequency of Reporting</i>	<i>Quarterly or Annually.</i>	<i>Frequency of report reporting.</i>	<i>Ad hoc</i>		

Effective Year: 2011

Requirement / Objective: Ensure adequate privacy and security protections for personal health information

Target (Definition): Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

Metrics					
Capability	Adoption	Utilization	Effectiveness	Barriers	Recommendations
Capability: Provide consumers, families and patients with security message outlining the security capabilities associated with system.	All (100%) consumers, patients and families receive appropriate security information upon contact or log in.	Provide consumers, families and patients with security message outlining the security capabilities associated with system.	Consumers, Families and patients report high confidence level with security of information.	1) weak passwords on part of consumer, family or patient. 2) Failure of consumer, family or patient to disengage from system, thereby leaving connection open	
<i>Data Source:</i>	<i>EHR</i>	<i>Patient login screen.</i>	<i>Security Surveys</i>		
<i>Form of Metric (data structure):</i>	<i>Yes/No Metric - reported by EHR vendor.</i>	<i>Yes/No Metric - reported by EHR vendor.</i>	<i>TBD</i>		
<i>Frequency of Reporting</i>	<i>Annually.</i>	<i>Annually.</i>	<i>Annually.</i>		

Effective Year: 2011

Requirement / Objective: Improving quality, safety, efficiency, and reducing health disparities. (p 103)

Target (Definition): Send reminders to patients per patient preference for preventive/follow up care

Metrics					
Capability	Adoption	Utilization	Effectiveness	Barriers	Recommendations
Capability: Provide consumers, families and patients with timely and secure messages detailing preventative and follow up care requirements.	All (100%) of consumers, patients and families receive preventative/follow up care message reminders	Consumers, patients and families receive member-appropriate preventative/follow up care message reminders	Members achieve a high compliance (90) level in meeting member appropriate preventative/follow up care.		
<i>Data Source:</i>	<i>EHR / E-mail</i>	<i>EHR / E-mail</i>	<i>EHR</i>		
<i>Form of Metric (data structure):</i>	<i># patients receiving follow-up care messages / total # patients</i>	<i># patients or designees receiving member-appropriate follow-up care messages / total # patients</i>	<i># patients acting on follow up message / # follow up messages</i>		
<i>Frequency of Reporting</i>	<i>Annually.</i>	<i>Annually.</i>	<i>Annually.</i>		

Effective Year:

Requirement / Objective: Patient Specific Educational Resources

Target (Definition): Provide consumers and patients with access to language appropriate resources and materials

Metrics					
Capability	Adoption	Utilization	Effectiveness	Barriers	Recommendations
Capability: Provide materials in patient's primary language at an appropriate reading level.	Materials available for top 50% of members of physician panel (or service area)		1) ____% of patients surveyed are aware of availability of materials. 2) Of patients who have read materials, ____% find them understandable.	(1) Technical complications on presentation of non Latin-based alphabets (Cyrillic, Chinese, Vietnamese, etc.) (2) Translation capability of hospital or physician office.	Recommend adoption of system similar to DMHC threshold language requirements for HP
	Hospital or EP Educational Materials or EHR		1) # patients aware of availability / # patients 2) # patients who find material understandable / # patients who have received and read materials.		
	# materials available / # patients in Panel or service area		Numerator and Denominator / Compilation		
	As requested		As requested		

Effective Year:

Requirement / Objective: Patient / Provider Secure Messaging

Target (Definition): Secure messaging capabilities between patients and providers

Metrics					
Capability	Adoption	Utilization	Effectiveness	Barriers	Recommendations
Capability: Provide consumers, families and patients with secure messaging capabilities with EP and Hospitals	All (100%) patient and provider inter-communications are security encrypted and transmitted.	Provide consumers, families and patients with secure messaging capabilities that are not financially burdensome to consumer, families and patient.	Consumers, Families and patients report high confidence level with data	1) weak passwords on part of consumer, family or patient. 2) Failure of consumer, family or patient to disengage from system, thereby leaving connection open	
<i>Data Source:</i>	<i>TBD</i>	<i>Provider or physician records</i>	<i>Patient / Family survey</i>		
<i>Form of Metric (data structure):</i>	<i>TBD</i>	<i>Yes/No Metric - reported by provider (capability exists and cost is not burdensome).</i>	<i># patients confident in data / # survey respondents</i>		
<i>Frequency of Reporting</i>	<i>As requested</i>	<i>Frequency of report reporting.</i>	<i>Frequency of report reporting.</i>		

Effective Year:

Requirement / Objective: Patients Have Access to Self Management Tools

Target (Definition): Provide patient with capability to take active role in their care and management

Metrics					
Capability	Adoption	Utilization	Effectiveness	Barriers	Recommendations
Capability: Provide members with access to medical information that is simple and easy to understand. Multiple delivery options such as interactive media available.	Members, patients provided with information notifying them of availability of Medical information for patient or family “at risk” conditions, chronic conditions made available to patient. Medical information on , medical procedures, recommended best practices available	80 % of patients (with computer access) consult self management tools			
<i>Data Source:</i>	<i>EHR / E-mail</i>	<i>PHR</i>			
<i>Form of Metric (data structure):</i>	<i># patients who receive notification that electronic info is available / total # of patients.</i>	<i># patients who log in to PHR / total # patients.</i>			
<i>Frequency of Reporting</i>	<i>As requested</i>	<i>As requested</i>			

Effective Year:

Requirement / Objective: Mobile Access to Electronic Health Info and Processes

Target (Definition): Availability of electronic Health information via mobile devices

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
Capability: Members/patients/families awareness of electronic health information availability via common mobile devices	Patient aware of capability.	Delivery of electronic health information made available to members via mobile device			
<i>Data Source:</i>	<i>Provider notes / communication materials.</i>	<i># patients desiring delivery of information via mobile device/# patients</i>	<i>List data source, validity</i>		
<i>Form of Metric (data structure):</i>	<i>Yes/No Metric - reported by provider.</i>	<i>Yes/No Metric - reported by provider.</i>	<i>Yes/No Metric - reported by provider.</i>		
<i>Frequency of Reporting</i>	<i>As requested</i>	<i>As requested</i>	<i>As requested</i>		

Effective Year:

Requirement / Objective: Upload Data from Remote Monitoring Devices

Target (Definition): Provide patients with ability to upload data from approved remote monitoring devices to upstream system.

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
Capability: Upload data from approved remote monitoring devices continuously without intervention from patient	% of remote monitoring devices with capability	% of patients where data is uploaded continuously to upstream system	Quality of upstream data. % of accurate device response to remotely captured events		
<i>Data Source:</i>	<i># remote monitoring devices that are uploadable / total # of monitoring devices.</i>	<i># patients uploading data from monitoring devices / # patients using monitoring devices</i>	<i>Independent QA.</i>		
<i>Form of Metric (data structure):</i>	<i>Numerator and Denominator / Compilation</i>	<i>Numerator and Denominator / Compilation</i>	<i>Accurate device response / total # device responses</i>		
<i>Frequency of Reporting</i>	<i>As requested</i>	<i>As requested</i>	<i>As requested</i>		

Effective Year:

Requirement / Objective: Patient Initiated Medication Refill Requests

Target (Definition): Provide patients with electronic access capabilities to initiate refill requests.

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
Capability: Provide patient with ability to initiate medical refill requests	% of hospitals or EPs who have the capability.	% of refill requests delivered electronically.	Patient receives prescription.	Small patient population with personal internet access.	This should be part of training and education of patients It should be identified as operational and material savings for covered entities.
<i>Data Source:</i>	<i>Providers notes / EHR</i>	<i>EHR</i>	<i>List data source, validity</i>		

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
<i>Form of Metric (data structure):</i>	<i># hospitals with capability / total # of hospitals in population being measured.</i>	<i># refill requests done electronically / total # refill requests.</i>	<i>TBD</i>		
<i>Frequency of Reporting</i>	<i>Frequency of report reporting.</i>	<i>Frequency of report reporting.</i>	<i>Frequency of report reporting.</i>		

Effective Year:

Requirement / Objective: Medication Lists and Information

Target (Definition): Provide patients with timely electronic access to their medication lists and information on medications

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
Capability: Provide patient with ability to view medication lists within 48 hrs of RX	% of hospitals or EPs who have the capability.	% of medical lists and medication information delivered electronically	Verified receipt and understanding of materials.	Small patient population with personal internet access.	This should be part of training and education of patients. It should be identified as operational and material savings for covered entities.
<i>Data Source:</i>	<i>List data source, validity</i>	<i>List data source, validity</i>	<i>List data source, validity</i>		
<i>Form of Metric (data structure):</i>	<i>Numerator and Denominator / Compilation</i>	<i>Numerator and Denominator / Compilation</i>	<i>Numerator and Denominator / Compilation</i>		
<i>Frequency of Reporting</i>	<i>Frequency of report reporting.</i>	<i>Frequency of report reporting.</i>	<i>Frequency of report reporting.</i>		

Effective Year:

Requirement / Objective: Access for All Patients to PHR with Real Time with Health Data

Target (Definition): Provide consumers, patients and families who have participated in PHR with real time access to data

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
Capability: Provide consumers with real time access to PHR data that includes relevant preventative information. Provide patients with real time access to PHR with relevant preventative and follow up data that coordinates with EHR	1) % of Consumers who participate in PHR 2) % of patients who participate in PHR that integrates with EP	% of EP's providing integrated PHR to patients and members	1) % of patients accessing PHR.		
<i>Data Source:</i>	<i># patients participating in PHR that integrates with EP / Total # patients</i>	<i># EP's providing PHR to patients / total # EP's</i>	<i>List data source, validity</i>		
<i>Form of Metric (data structure):</i>	<i>Numerator and Denominator / Compilation</i>	<i>Numerator and Denominator / Compilation</i>	<i>Numerator and Denominator / Compilation</i>		

Metrics				Barriers	Recommendations
Capability	Adoption	Utilization	Effectiveness		
<i>Frequency of Reporting</i>	<i>As requested.</i>	<i>As requested.</i>	<i>As requested.</i>		

11.3.2 Technical Infrastructure Performance Measures

The TWG and TAC developed a set of evaluation questions related to the goals and principles of the workgroup. The GE and Evaluator will work to develop specific measures for the technical performance of the HIE.

- Is the Statewide technical architecture for HIE developed and ready for implementation according to HIE model(s) chosen by the governance organization?
- Does Statewide technical infrastructure integrate State-specific Medicaid management information systems?
- Does Statewide technical infrastructure integrate regional HIE?
- What proportion of healthcare providers in the State are able to send electronic health information using components of the HIE Technical infrastructure?
- What proportion of healthcare providers in the State are able to receive electronic health information using components of the HIE Technical infrastructure?
- What percentage of providers with EHRs are achieving meaningful use utilizing State HIE services?

11.3.3 Governance Entity Performance Measures

The GE has a set of performance measures for its own convening, coordinating, and managing functions; and is additionally responsible for the performance of Business and Technical Operations and adherence to Legal and Policy Requirements.

- What proportion of the governing organization is represented by public stakeholders?
- What proportion of the governing organization is represented by private sector stakeholders?
- Does the governing organization represent government, public health, hospitals, employers, providers, payers and consumers?
- Does the State Medicaid agency have a designated governance role in the organization?

- Has the governing organization adopted a strategic plan for Statewide HIT?
- Has the governing organization approved and started implementation of an operational plan for Statewide HIT?
- Are governing organization meetings posted and open to the public?
- Do regional HIE initiatives have a designated governance role in the organization?
- Is technical assistance available to those developing HIE services?
- What percentage of the State does not yet have access to HIE services?
- How many HIOs have been assisted by the GE?
- How many HIOs have failed and for what reason(s)?
- How do the forecasted number of transactions for each shared service compare with their actual use?
- How many educational and outreach sessions has the GE performed and how many individuals attended?
- How effective was the marketing effort to consumers and providers according to the metrics outlined in the Communications Plan?
- Is the Statewide governance organization monitoring and planning for remediation of HIE as necessary throughout the State?
- What percent of health care providers have access to broadband?
- What Statewide shared services or other Statewide technical resources are developed and implemented to address business and technical operations?
- Has the governance organization developed and implemented privacy policies and procedures consistent with State and federal requirements?
- How many trust agreements have been signed?

- Do privacy policies, procedures and trust agreements incorporate provisions allowing for public health data use?

APPENDICES

Appendix 1: Glossary

American Recovery and Reinvestment Act of 2009 (ARRA): is a \$787.2 billion stimulus measure, signed by President Obama on February 17, 2009, that provides aid to States and cities, funding for transportation and infrastructure projects, expansion of the Medicaid program to cover more unemployed workers, health IT funding, and personal and business tax breaks, among other provisions designed to “stimulate” the economy.

Centers for Medicare and Medicaid Services (CMS): is a federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with State governments to administer Medicaid, the State Children’s Health Insurance Program (SCHIP), and health insurance portability standards.

Certification Commission for Healthcare IT (CCHIT): is a recognized certification body (RCB) for electronic health records and their networks. It is an independent, voluntary, private-sector initiative, established by the American Health Information Management Association (AHIMA), the Healthcare Information and Management Systems Society (HIMSS), and The National Alliance for Health Information Technology.

Consent: The Health Insurance Portability and Accountability Act Privacy Rule sets out two types of permission that are used to permit a covered entity to use or disclose protected health information: consent and authorization. A written “authorization” is required in certain circumstances, including for most disclosures of psychotherapy notes; to disclose health information for “marketing”; and for uses and disclosures that are not otherwise required or permitted by the privacy regulation. The Privacy Rule, however, generally permits a covered entity to use and disclose protected health information without an individual’s authorization for treatment, payment and health care operations, and certain other specified purposes.

The Privacy Rule includes detailed requirements for the authorization form that must be used to obtain authorization when required. All authorization forms must contain certain core elements, including:

- A specific description of the information to be used or disclosed and the purposes of the use or disclosure;
- The identity of the person or class of persons authorized to make the requested use or disclosure;
- The identity of the person or class of persons to whom the covered entity may make the requested use or disclosure;
- A Statement of the person's right to revoke the authorization; and
- The signature and date of the authorization.

A general "consent" is permitted but not required for use or disclosure of information for treatment, payment, and health care operations. Covered entities that choose to obtain a patient's consent for use or disclosure of information for treatment, payment, and health care operations have complete discretion in designing their consent form and process. The regulation does not define the term "consent" and does not specify any requirements for the content of consent forms.

Consumer: the universe of patients or potential patients; any individual who has consumed a health product or service or is likely to require attention from health service providers at some point in his or her life span.

Electronic Health Record (EHR): As defined in the ARRA, an Electronic Health Record (EHR) means an electronic record of health-related information on an individual that includes patient demographic and clinical health information, such as medical histories and problem lists; and has the capacity to provide clinical decision support; to support physician order entry; to capture and query information relevant to health care quality; and to exchange electronic health information with, and integrate such information from other sources.

Electronic Prescribing (ePrescribing): A type of computer technology whereby physicians use handheld or personal computer devices to review drug and formulary coverage and to transmit prescriptions to a printer or to a local pharmacy. E-prescribing software can be integrated into existing clinical information systems to allow physician access to patient-specific information to screen for drug interactions and allergies.

Eligible Provider: as defined in ARRA, eligible providers include physicians, dentists, nurse mid-wives and nurse practitioners, or physician assistants (practicing in a federally qualified health center or rural health clinic led by a physician assistant.)

Family: persons designated by a consumer as their personal representative to be entitled to access the consumer's electronic records through HIE. (In the case of a minor, persons deemed by the State to be responsible for that individual.)

Federal Communications Commission (FCC): is the United States government agency charged with regulating interstate and international communications by radio, television, wire, satellite and cable.

Federally-Qualified Health Centers (FQHCs): are "safety net" providers such as community health centers, public housing centers, outpatient health programs funded by the Indian Health Service, and programs serving migrants and the homeless. FQHCs provide their services to all persons regardless of ability to pay, and charge for services on a community board approved sliding-fee scale that is based on patients' family income and size. FQHCs are funded by the federal government under Section 330 of the Public Health Service Act.

Governance Entity (GE): For the State of California, the Governance Entity is the State Designated Entity. (See definition for State Designated Entity.)

Health Consumer: an individual who self-selects for interest in health-related information, for participation in health-related groups or electronic conversations, for accessibility to marketing of health-related products.

Health Information Exchange (HIE): As defined by the Office of the National Coordinator and the National Alliance for Health Information Technology (NAHIT), Health Information Exchange means the electronic movement of health-related information among organizations according to nationally recognized standards.

Health Information Technology (Health IT or HIT): As defined in the ARRA, Health Information Technology means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.

Health Information for Economic and Clinical Health (HITECH) Act: collectively refers to the health information technology provisions included at Title XIII of Division A and Title IV of Division B of the ARRA.

Health Insurance Portability and Accountability Act (HIPAA): was enacted by Congress in 1996. Title I of HIPAA protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The Administrative Simplification provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in the U.S. health care system.

Health Information Organization (HIO): An organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.

Healthcare Information Technology Standards Panel (HITSP): A multi-stakeholder coordinating body designed to provide the process within which stakeholders identify, select, and harmonize standards for communicating and encouraging broad deployment and exchange of healthcare information throughout the healthcare spectrum. The Panel's processes are business process and use-case driven, with decision making based on the needs of all NHIN stakeholders. The Panel's activities are led by the American National Standards Institute (ANSI), a not-for-profit organization that has been coordinating the U.S. voluntary standardization system since 1918.

Interface: A means of interaction between two devices or systems that handle data.

Interoperability: Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities.

Medi-Cal: Medi-Cal is California's Medicaid program. This is a public health insurance program which provides needed health care services for low-income individuals including families with children, seniors, persons with disabilities, foster care, pregnant women, and low income people with specific diseases such as tuberculosis, breast cancer or HIV/AIDS. Medi-Cal is financed equally by the State and federal government.

Meaningful EHR User: As set out in the ARRA, a Meaningful EHR user meets the following requirements: (i) use of a certified EHR technology in a meaningful manner, which includes the use of electronic prescribing; (ii) use of a certified EHR technology that is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care; and (iii) use of a certified EHR technology to submit information on clinical quality and other measures as selected by the Secretary of HHS.

Nationwide Health Information Network (NHIN): A national effort to establish a network to improve the quality and safety of care, reduce errors, increase the speed and accuracy of treatment, improve efficiency, and reduce healthcare costs.

Notification: While the term notification is not directly contemplated in Health Insurance Portability and Accountability Act, the concept of providing notice of privacy practices is. The Privacy Rule requires a covered entity to provide individuals with a written notice describing the entity's privacy practices. Health plans are required to give notice at enrollment and to notify individuals every three years that the privacy practices notice is available. Providers that have a direct treatment relationship with an individual are only required to give notice at the date of the first service delivery; and except in emergency circumstances, must make a good faith effort to obtain a written acknowledgment from the individual of receipt of the notice. Providers must also have notice posted on the premises. Both plans and providers have special notice requirements if their privacy practices change. Clearinghouses acting as business associates of another covered entity are not required to give notice to patients. The notice must include:

- A description of an individual's rights with respect to protected health information and how the individual may exercise those rights;
- The legal duties of the covered entity;
- A description of the types of uses and disclosures of information that are permitted, including those that are permitted or required without the individual's written authorization;
- How an individual can file complaints with the covered entity and the Secretary of HHS;
- How the covered entity will provide the individual with a revised notice if the notice is changed;
- A contact person for additional information; and

- The date on which the notice is in effect.

Office of the National Coordinator (ONC): serves as principal advisor to the Secretary of HHS on the development, application, and use of health information technology; coordinates HHS's health information technology policies and programs internally and with other relevant executive branch agencies; develops, maintains, and directs the implementation of HHS' strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors, to the extent permitted by law; and provides comments and advice at the request of OMB regarding specific Federal health information technology programs. ONC was established within the Office of the Secretary of HHS in 2004 by Executive Order 13335.

Patient: any consumer known to health service providers because care has been provided, or planned.

Personal Health Information (PHI): As defined by HIPAA, any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment.

Privacy: In December 2008, the Office of the National Coordinator for Health IT released its "Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information," ("Framework") in which it defined privacy as, "An individual's interest in protecting his or her individually identifiable health information and the corresponding obligation of those persons and entities that participate in a network for the purposes of electronic exchange of such information, to respect those interests through fair information practices." This language contrasts with the definition of privacy included in the National Committee on Vital and Health Statistics' ("NCVHS") June 2006 report, entitled, "Privacy and Confidentiality in the Nationwide Health Information Network." In its report, NCVHS recommended the following definition for "privacy": "Health information 'privacy' is an individual's right to control the acquisition, uses, or disclosures of his or her identifiable health data."

Regional Health Information Organization (RHIO): A health information organization that brings together healthcare stakeholders within a defined geographic area and governs health information exchange among them for the purpose of improving health and care in that community.

Regional Health Information Technology Extension Centers (RHITECs): As set out in the ARRA, Regional Health Information Technology Extension Centers will be established and may qualify for funding under ARRA to provide technical assistance and disseminate best practices and other information

learned from the Health Information Technology Research Center to aid health care providers with the adoption of health information technology.

State-Designated Entities (GEs): As defined in the ARRA, State-Designated Entities (GEs) may be designated by a State as eligible to receive grants under Section 3013 of the ARRA. To qualify as an GE, an entity must be a not-for-profit entity with broad stakeholder representation on its governing board; demonstrate that one of its principal goals is to use information technology to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information; adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation by stakeholders; and conform to other requirements as specified by HHS.

Security: The Health Insurance Portability and Accountability Act Security rule defines “Security or Security measures” as “encompass[ing] all of the administrative, physical, and technical safeguards in an information system.

Two-Factor Authentication: An authentication factor is a piece of information and process used to authenticate or verify the identity of a person or other entity requesting access under security constraints. Two-factor authentication is a system wherein two different factors are used in conjunction to authenticate. Using two factors as opposed to one factor generally delivers a higher level of authentication assurance. Two-factor authentication typically is a signing-on process where a person proves his or her identity with two of the three methods: “something you know” (e.g., password or PIN), “something you have” (e.g., smartcard or token), or “something you are” (e.g., fingerprint or iris scan).

U.S. Department of Health and Human Services (HHS): is the federal government agency responsible for protecting the health of all Americans and providing essential human services. HHS, through CMS, administers the Medicare (health insurance for elderly and disabled Americans) and Medicaid (health insurance for low-income people) programs, among others.

Appendix 2: Acronyms Used

ARRA:	American Recovery and Reinvestment Act
ASTM:	American Society for Testing and Materials
BHIX:	Brooklyn Health Information Exchange
CAAT:	California ARRA and Accountability Tool
CAIR:	California Automated Immunization Registry
CalHIPSO:	California Health Information Partnership and Services Organization (formerly Cal-REC.)
CalOHII:	Office of Health Information Integrity
CalPSAB:	California Privacy and Security Advisory Board
CalREDIE:	California Reportable Disease Information Exchange
CALSTARS:	California State Accounting and Reporting System
CAPH:	California Association of Public Hospitals
CAQH:	Council for Affordable Quality Healthcare
CCD:	Continuity of Care Document
CCF:	Community Care Facility
CCMS:	California Court Case Management System (CCMS)
CCR:	Continuity of Care Record
CDC:	Centers for Disease Control and Prevention
CDPH:	California Department of Public Health
CFDA:	Catalog of Federal Domestic Assistance
CHA:	California Hospital Association
CHCF:	California Health Care Foundation
CHDP:	Child Health and Disability Prevention
CHFFA:	California Health Facilities Financing Authority
CHHS:	California Health and Human Services Agency
CHWA:	California Health Workforce Alliance
CMIPS:	Case Management Information and Payrolling System
CMR:	Confidential Morbidity Reporting
CMS:	Centers for Medicare and Medicaid Services
CMS:	Case Management System (in context of CWS)
CORE:	Committee on Operating Rules for Information Exchange
CPCA:	California Primary Care Association
CR:	Controller's Receipt
CSRHA:	California State Rural Health Association
CTEC:	California Telemedicine and eHealth Center
CTN:	California Telehealth Network
CVX:	Clinical Vaccine Codeset Names
CWS:	Child Welfare Services
DHCS:	Department of Health Care Services
DURSA:	Data Use and Reciprocal Support Agreement
EARS:	Early Aberration Reporting System
ED:	Emergency Department
EDI:	Electronic Data Interchange
EHR:	Electronic Health Record
ELINCS:	EHR-Lab Interoperability and Connectivity Specification
ELR:	Electronic Lab Reporting
FCC:	Federal Communications Commission

FCN:	Federal Catalog Number
FQHC:	Federally Qualified Health Center
GE:	Governance Entity
HEAL-NY:	Healthcare Efficiency and Affordability Law for New Yorkers
HEDIS:	Healthcare Effectiveness Data and Information Set
HEP:	Health and Education Passport
HHS:	United States Department of Health and Human Services
HIE:	Health Information Exchange
HIO:	Health Information Organization
HIPAA:	Health Insurance Portability and Accountability Act
HIT:	Health Information Technology
HITECH:	Health Information Technology for Economic and Clinical Health Act, part of ARRA.
HITFAC:	Health Information Technology Financing Advisory Commission
HITSP:	Healthcare Information Technology Standards Panel
HL7:	Health Level 7
HMO:	Health Maintenance Organization
ICD-9 or ICD-10:	International Classification of Diseases, version 9 or 10
ICU:	Intensive Care Unit
IDN:	Integrated Delivery Network
IFR:	Interim Final Rule
IFR:	Interim Final Rule
IPA:	Integrated Practice Associations
IPSec:	Internet Protocol Security
LEC:	Local Extension Center
LOINC:	Logical Observation Identifiers Names and Codes
Medi-Cal:	California Medicaid Program.
MITA:	Medicaid Information Technology Architecture
MMIS:	Medicaid Management Information System
MOU:	Memorandum of Understanding
NACO:	National Association of County Officers
NAPHSIS:	National Association for Public Health Statistics and Information Systems
NCVHS:	National Committee on Vital and Health Statistics
NGA:	National Governors' Association
NHIE:	Nationwide Health Information Exchange
NHIN:	Nationwide Health Information Network
NICU:	Neonatal Intensive Care Unit
NIST:	National Institute of Standards and Technology
NPI:	National Provider Identifier
NPRM:	Notice of Proposed Rulemaking
OASE:	Office of State Audits and Evaluation
OCIO:	State Chief Information Officer
OHIT:	Office of Health Information Technology (California)
OMB:	Office of Management and Budget
ONC:	Office of the National Coordinator for Health Information Technology
P/N:	Project Number
PBM:	Pharmacy Benefits Management
PHIN:	Public Health Information Network
PHR:	Personal Health Record
PPO:	Preferred Provider Organization
REC:	Regional Extension Center

RHIO:	Regional Health Information Organization
RHITEC:	Regional Health Information Technology Extension Center (same as REC)
RODS:	Real Time Outbreak Disease Surveillance
SACWIS:	Statewide Automated Child Welfare Information System
SAML:	Security Assertion Markup Language
SAWS:	Statewide Automated Welfare
SBHC:	School-Based Health Care
SCO:	State Controller's Office
SEFA:	Schedule of Expenditures of Federal Awards
SHARP:	Strategic HIT Advanced Research Projects Program
SIIS:	Statewide Immunization Information System
SMS:	Short Message Service
SNOMED:	Systematized Nomenclature of Medicine
SOAP:	Simple Object Access Protocol
SOP:	Standard Operating Procedure
STEVE:	State and Territorial Exchange of Vital Events
TAC:	Technical Advisory Committee
TRC:	Telehealth Resource Center
TLS:	Transport Layer Security
TWG:	Technical Working Group
UDDI:	Universal Description Discovery Interface
UHC:	United Health Care
URI:	Uniform Resource Identifier
URL:	Uniform Resource Locator
WSDL:	Web Services Description Language

Appendix 3: Workgroup Charters, Rosters, and Biographies of Chairs

Workgroup Chair Biographies

Vulnerable and Underserved Workgroup

- **Steve Barrow** is Policy Director at the California State Rural Health Association, bringing an in-depth knowledge of the challenges facing rural populations. He is also involved in the immunization registry through his work as a Board of Directors Member of CA Immunization Coalition (CIC) and Co-Chair of the CIC Advocacy/Legislative Committee and the group's Secretary Treasurer.
- **Stephanie Oprende** is a Senior Associate at the California Institute for Mental Health, a Board Member of the American College of Mental Health Administration, and formerly of the CA Department of Mental Health. She was involved in the development of the California Health IT Strategic Plan this summer, focusing on the inclusion of behavioral health needs.

Patient Engagement Workgroup

- **Albert Chan, MD** brings the provider perspective, drawing on a wealth of expertise in clinical operations and HIT implementations. Currently at Palo Alto Foundation Medical Group, he is the Physician Champion for their ambulatory EHR and the Medical Director of Health Information Management, directing a physician optimization team to provide strategy and change management leadership for EHR and PHR innovations.
- **Larry Stofko** is the Chief Information Officer and Senior Vice President at St. Joseph's Health System, 14-hospital, \$3.7 billion not-for-profit Catholic health system. Larry contributes an experienced view of the institutional perspective on EHR adoption and participation in HIE services, understanding organizational priorities and needs as well as the care delivery system's interactions with patients and their families.
- **Mike Kirkwood**, is the Chief Executive Officer of Polka, a secure mobile personal health platform that allows users to manage their health and wellness, brings the consumer and innovation perspective to this group. An active leader in the Health 2.0 innovation and entrepreneur community, Mike has more than 15 years experience in creating and adapting usable technologies and applications that patients and their families can use to improve their health.

Finance Workgroup

- **Steven Henry** is the Director of Treasury Investment Management at UnitedHealth Group. Steven has been with United Health Group for over 12 years and has played a key role as a co-chair of the State's EHR Loan Fund workgroup and contributor to the eHealth strategic plan.
- **Dr. Larry Ozeran** is a lifelong Californian who provides routine and emergency surgical services to medically underserved Yuba and Sutter county residents. He has been a software engineer for over 30 years and an advocate for healthcare reform for more than a decade. Dr. Ozeran serves as Chair of the Yuba-Sutter Healthcare Council (YSHC), promoting the most effective use of limited healthcare resources. He is leading the YSHC in a project to explore and possibly establish a regional HIO. Dr. Ozeran is an Associate Clinical Professor at UC Davis in the Health Informatics Program with a focus on social, organizational and political issues. He is also President of Clinical Informatics, Inc. which promotes optimal use of technology in clinical practice.

Technical Advisory Committee and Technical Working Group

Co-Chair of Technical Working Group

- **Scott Cebula** is President and Managing Member of Cebula IT Consulting LLC, a healthcare IT firm covering Southern California. He is a co-chair of the California HIE Technical Working Group and a board member for OCPRHIO (Orange County's Health Information Exchange). Scott has been in healthcare IT for twenty years, having starting his career as a Fortune 500 consultant. He has a B.S. in Mechanical Engineering from Cal, and post graduate work in Aerospace Engineering at USC (where he also served as adjunct faculty for the MHA program). Prior to forming his firm, , Scott was affiliated with several leading Southern California health systems and hospitals. He served as CIO for Huntington Memorial Hospital, CTO for St. Joseph Health System, and VP of Information Services for MemorialCare. He is privileged to have been associated with facilities that won two innovation awards and six consecutive 'Most Wired' awards.

Co-Chair of the Technical Working Group

- **Wayne Sass** serves as Vice President, Chief Information Officer, and Privacy Officer for Nautilus Healthcare Management Group, LLC with overall responsibility for Corporate

Information Services, Systems Development, I.S. Operations, Process Improvement, Project Management Office, Business Continuity Program, Eligibility, Benefits, Provider Pricing, Decision Support, Clinical Analytics, HCC/RAF Data Support, HIPAA Compliance, liason with outside counsel, and Government Affairs. Nautilus Healthcare Management Group is a Newport Beach-based management services organization (MSO). Nautilus provides management services to physician organizations and provider practices. Nautilus' physician organization clients include Greater Newport Physicians, Edinger Medical Group, Cedars-Sinai Health Associates and Cedars-Sinai Medical Group; all among the top ranked physician organizations in the State. Nautilus Physician Services offers a comprehensive range of practice management services ranging from billing only to full practice management, including EHR implementation and support, for more than 160 Orange County providers in almost 60 practices. Before the formation of Nautilus, Wayne served as the Chief Information Officer and Privacy Officer for Greater Newport Physicians Medical Group, Inc. Wayne is also the former Vice President of Information Technology for DaVita Inc, the country's largest for-profit provider of dialysis services. In that role he was responsible for DaVita's enterprise IT infrastructure supporting its nationwide network of outpatient dialysis clinics.

Other Contributors

- **Walter Sujansky** is the President of Sujansky & Associates, a consulting firm that specializes in the representation, analysis, and exchange of clinical data in information systems. Dr. Sujansky serves as the technical lead on the ELINCS project, a national initiative to standardize the electronic reporting of laboratory test results to EMR systems. Dr. Sujansky has also provided technical leadership in the development of data-interchange standards and data-integration techniques for the California Clinical Data Project, a State-wide initiative to measure and improve chronic disease care through information technology.

Workgroup Rosters

Technical Advisory Committee	
Name	Organization
Andrews, Tim	High Pine Associates, LLC
Beighe, Bill	Physicians Medical Group of Santa Cruz
Calhoun, Zan	Healthcare Partners
Christman, Scott	CA Dept. of Public Health
Cooper, Crystal	OSI

Technical Advisory Committee

Name	Organization
Coye, Molly	CalRHIO
Doebbert, Gwendolyn	CHHS
Franklin, Greg	Medi-Cal
Frohlich, Jonah	California Health and Human Services Agency
Guterman, Jeff	LA County Dept. of Health Services
Hearn, Terry	Wellpoint
Holm, Bobbie	CHHS- CalOHII
Hung, Peter	Sujansky & Associates, LLC
Jimenez, Ron	Santa Clara Valley Health & Hospital System
Joslyn, Scott	MemorialCare
Joyner, David	Blue Shield of California
Kennedy, Charles	Blue Cross of California
Khalsa, Rama	Santa Cruz County
Khan, Sainam	Altamed
Landry, Laura	Long Beach Network for Health
Lindsay, Ann	California Conference of Local Health Officers
Mattison, John	
McGovern, Greg	Adventist Health
Minear, Michael	UC Davis Health System
Moy, Glen	California HealthCare Foundation
Ortiz, Kim	Medi-Cal
Otake, Ray	Community Health Center Network
Parris, Ray	Golden Valley Health Centers
Quinlan, Christy	CA Office of the State Information Officer (OCIO)
Rieger, Debbie	CalRHIO
Roberts, Angela	Altamed
Sass, Wayne	Nautilus Healthcare Management Group
Savage, Lucia	UnitedHealthcare
Schmoeckel, Christine	CHHS- CalOHII
Schrader, Michael	CenCal Health
Scott, Linette	CA Dept. of Public Health
Shaw, Terri	The Children's Partnership
Shima, Sheila	County of Los Angeles
Soon-Shiong, Patrick	National Coalition for Health Integration
Spooner, Bill	Sharp HealthCare
Strydom, Elfreda	Sujansky & Associates, LLC
Sujansky, Walter	Sujansky & Associates, LLC
Whyte, Scott	Catholic Healthcare West
Williams, Tom	Integrated Healthcare Association
Young, Kris	CA Office of Health Information Integrity

Technical Working Group

Name	Organization
Andrews, Tim	High Pine Associates, LLC
Bass, Dave	CA Dept. of Health Care Services

Technical Working Group

Name	Organization
Brown, Jane	Nautilus Healthcare Management Group
Cebula, Scott	
Chaudhry, Basit	National Coalition for Health Integration
Christman, Scott	CA Dept. of Public Health
Collins, Paul	CA Dept. of Public Health
Cooper, Crystal	OSI
Cothren, Robert	California eHealth Collaborative
Doebbert, Gwendolyn	CHHS
Dworkin, Darren	Cedars-Sinai Medical Center
Evoy, Jeff	Sharp Community Medical Group
Frohlich, Jonah	California Health and Human Services Agency
Goltz, Amanda	Manatt Health Solutions
Hammond, Larry	California Department of Health Care Services
Handren, Dave	Long Beach Network for Health
Haun, Daniel	Adventist Health
Holm, Bobbie	CHHS- CalOHII
Hung, Peter	Sujansky & Associates, LLC
Khayat, Alex	Huntington Hospital
Lowell, Kathryn	CA Business, Transportation and Housing Agency
Minch, Dave	John Muir Health System
Mosbrucker, Lee	CA Office of the Chief Information Officer
Moscaritolo, Eileen	CalOptima
Ortiz, Kim	Medi-Cal
Portale, Orlando	Palomar Pomerado Health District
Saunders, Steve	LA County Health Services
Schmoeckel, Christine	CHHS- CalOHII
Stever, Anthony	aws Consulting Services / Central Valley Health Network
Strydom, Elfreda	Sujansky & Associates, LLC
Sujansky, Walter	Sujansky & Associates, LLC
Thornton, Jim	MemorialCare
Word, Ben	California Department of Health Care Services
Young, Kris	CA Office of Health Information Integrity

Finance Workgroup

Name	Organization
Ahmed, Sajid	
Allaire, Roger	Accenture
Arzt, Noam	HLN Consulting, LLC
Bair, Yali	Planned p
Barcellona, William	CAPG
Barr, Lynn	CHHS
Barr, Justin	
Beltramini, Mary Kay	CSC
Berg, Constance Connie""	CMB CONSULTING

Finance Workgroup	
Name	Organization
Burns, Rena	IBM
Carlos, Lawrence	Accenture Public Sector Health
Chan-Sawin, Lisa	Senate Health Committee
Chaudhry, Iftikhar	
Chen, Jay	
Chiea, Renee	Department of Managed Health Care
Crane, Donald	CAPG
Cucchi, Jerry	Front Porch
Dave', Ash	Mission Community Hospital
Dennis, Lyman	El Dorado Health Consulting
Devon, Martin	Long Beach Network for Health
Doebbert, Gwendolyn	CHHS
Dworkin, Darren	Cedars-Sinai Medical Center
Ehnes, Cindy	
Farsi, Maral	California Association of Health Plans
Filkins, Barbara	
Forster MD, Robert	HP
Frohlich, Jonah	California Health and Human Services Agency
frost, jennifer	CalRHIO
Galstian, Christina	Renta-CEO, Inc.
Gilmore, Lora	
Giorgi, Suzanne	CHHS- CalOHII
Goltz, Amanda	Manatt Health Solutions
Grause, Henry	Profectus Health Research
Gregory, Mary	California Association of Public Hospitals
Hack, Lori	Object Health
Hearn, Terry	Wellpoint
Henderson, Duane	Henderson Consulting
Henry, Steven	UnitedHealth Group
Katter, Bob	RelayHealth
Keet, Glenn	Axolotl Corp.
Ketchel, Alana	CHHS
Khayat, Alex	Huntington Hospital
Kim, David	
Landry, Laura	Long Beach Network for Health
Lane, Pamela	California Hospital Association
Lansky, David	PBGH
Lassiter, Robert	Axolotl Corp
Leahy, Kevin	CHHS- CalOHII
Leeruangsi, Ron	Los Angeles County Chief Executive Office
Lowell, Kathryn	Business, Transportation and Housing
Lutkenhouse, Dan	
Lynch, Patricia	Kaiser Permanente
Manni, Karma	CHFFA
Matthews, Mason	Los Angeles County Chief Executive Office

Finance Workgroup

Name	Organization
Mazanec, Nic.	CHHS- CalOHII
McDonald, Joe	NaviNet
Moscaritolo, Eileen	CalOptima
Murchinson, Julie	Manatt Health Solutions
Newman, Jeff	
Newman, Jeff	
Nunez, Lisa	Los Angeles County Chief Executive Office
Ozeran, Larry	Clinical Informatics, Inc
Patel, Bhavik	
Pulse, Kathy	Chancellor's Office, CA Comm Colleges
Ray, Joseph	Manatt Health Solutions
Rieger, Debbie	CalRHIO
Rogers, William	I-Medicus, Inc.
ross, will	
Samarin, Gary	CalOptima
Saran, Sunny	
Sass, Wayne	Nautilus Healthcare Management Group
Schamus, Mary	MIS4Health
Schmoeckel, Christine	CHHS- CalOHII
Shima, Sheila	County of Los Angeles
Siddiqui, Adil	Orange County Healthcare Agency
Spooner, Bill	Sharp HealthCare
Stever, Anthony	aws Consulting Services / Central Valley Health Network
Sullivan, Colleen	
Tremaine, Eileen	Tremaine Consulting
Verbeten, Nileen	Nileen Verbeten
Wallis, Kier	Manatt Health Solutions
weinberg, david	self
Yang, Thomas	

Vulnerable and Underserved Workgroup

Name	Organization
Barr, Justin	
Barr, Lynn	CHHS
Barrow, Steve	CA State Rural Health Association
Brooks, Susan	Shasta County Mental Health
Burns, Rena	IBM
Carlos, Lawrence	Accenture Public Sector Health
charbakshi, stella	county of San Mateo
Chen, Jay	
Christy, Jack	Aging Services of CA
Coblentz, Eva	CHHS- CalOHII
Convertino, Frank	CentriHealth
Crane, Donald	CAPG

Vulnerable and Underserved Workgroup

Name	Organization
Cucchi, Jerry	Front Porch
Delaney-Greenbaum, Kathleen	CHHS- CalOHII
Doebbert, Gwendolyn	CHHS
Dowdy, Eric	Aging Services of California
Duran, Eric	Placer County, HHS-MIS
Frohlich, Jonah	California Health and Human Services Agency
frost, jennifer	CalRHIO
Galstian, Christina	Renta-CEO, Inc.
Gluckman, Stefanie	The Childrens Partnership
Goltz, Amanda	Manatt Health Solutions
Gregory, Mary	California Association of Public Hospitals
Heerdink, Jennifer	Accenture Public Sector Health
Helvey, John	Victor Family of Services
Keswick, Memo	Behavioral Health Consultant
Ketchel, Alana	CHHS
Lansky, David	PBGH
Lassiter, Robert	Axolotl Corp
Leahy, Kevin	CHHS- CalOHII
Lee, Yvonne	CA Dept Social Services
Lovejoy, Arlene	LAC+USC Medical Center
Markell, Harriet	CCCMHA
martinez, andie	
Melli, Becki	
Meshar, Helyne	CAADPE
Morton, Doug	San Diego Blood Bank
Murray, William	Orange County Healthcare Agency BHS
Nishihama, John	County of Merced Department of Mental Health
Oprendeck, Stephanie	California Institute for Mental Health
Pennington, Brian	Netsmart Technologies
Platton, David	Krassons, Inc.
Quist, Ryan	Riverside County Dept of Mental Health
Ray, Joseph	Manatt Health Solutions
Refowitz, Mark	Orange County Healthcare Agency
ROBINSON, SHARON	Merced County Department of Mental Health
Sanson, Will	California Department of Social Services
Savage, Mark	Consumers Union of United States, Inc.
Schmoeckel, Christine	CHHS- CalOHII
Schoenberg, Melanie	California Association of Public Hospitals
Senella, Al	
Sharkey, Siobhan	Health Management Strategies, Inc.
Shaw, Terri	The Children's Partnership
Sheldon, Meg	County Welfare Directors Assoc. of Calif.
Siddiqui, Adil	Orange County Healthcare Agency
Smith, Donley	The Echo Group
Solomon, Cynthia	FollowMe/CHRD

Vulnerable and Underserved Workgroup

Name	Organization
Sorg, Jim	Tarzana Treatment Centers / CAADPE/ Long Beach Network for Health
Speer, Judy	DDSD
Stafford, Jane	Community Clinics Initiative
Stahl, Thomas	Community Care Licensing Division
Stovall, Heidi	MiVIA
WILDLAKE, CHRISTINA	
Yim, Donna	County of San Joaquin Behavioal Health Services

Patient Engagement Workgroup

Name	Organization
Bair, Yali	Planned p
Barr, Justin	
Barr, Lynn	CHHS
Brady, John	Life Alert Emergency Response
Brant-Lucich, Kim	St. Joseph Health System
Brenner, Claudia	Mahkor
Carter, Dan	CSC
Chan, Judy	HealthPro Consulting
Chan, Albert	Palo Alto Medical Foundation
charbakshi, stella	
Chen, Jay	
Coblentz, Eva	CHHS- CalOHII
Convertino, Frank	CentriHealth
Crane, Donald	CAPG
Denning, John	
Dickey, Larry	
Dietz, Harriett	San Francisco Towers
Doebbert, Gwendolyn	CHHS
Duffy, Patricia	Regional Health Occupations Resource Center
Evans, Douglas	Presidio Health, Inc
Filkins, Barbara	
Forster MD, Robert	HP
Frohlich, Jonah	California Health and Human Services Agency
frost, jennifer	CalRHIO
Galstian, Christina	Renta-CEO, Inc.
Gelbard, Marie-Claire	
Gmail Goltz, Gmail Amanda	Amanda's Personal Email
Goltz, Amanda	Manatt Health Solutions
Harper, Heather	Edelman
Hawkins, Adam	DrFirst - ePrescribing & MedHx
Hawkins, Lura	
Hipskind, Francine	Tulare Kings Counties Foundation for Medical Care
Holt, Matthew	Health 2.0
Hunt, Karen	CalRHIO
Johns MPH, Lucy	Health Care Planning and Policy

Patient Engagement Workgroup	
Name	Organization
Katter, Bob	RelayHealth
Kattlove, Jenny	The Children's Partnership
Kehoe, Linda	Northern Sierra Rural Health Network
Ketchel, Alana	CHHS
Khayat, Alex	Huntington Hospital
Kirkwood, Mike	Polka
Lansky, David	PBGH
Leahy, Kevin	CHHS- CalOHII
Leslie, Timathie	
Love, Barbara	Palo Alto Medical Foundation
Mandas, Jim	Healthcare Partners
Matyi, Michelle	Planned Parenthood Pasadena & San Gabriel Valley
McDonald, Joe	NaviNet
Means, Shannon	CA State Rural Health Association
Murchinson, Julie	Manatt Health Solutions
O'Donnell, Sean	
Oliva, Geraldine	
OSullivan, Maryann	
Pan, Wayne	Affinity Medical Solutions
Pleskow, Rochelle	
Raff, Robin	ECI Healthcare
Ray, Joseph	Manatt Health Solutions
Salgaonkar, Atul	PreviMed, Inc.
Sass, Wayne	Nautilus Healthcare Management Group
Savage, Mark	Consumers Union of United States, Inc.
Schamus, Mary	MIS4Health
Schmoeckel, Christine	CHHS- CalOHII
Seiler, Gregory	BeWell Mobile Technology, Inc.
Shaw, Terri	The Children's Partnership
Solomon, Cynthia	FollowMe/CHRDC
Stevenson, Teresa	CalOptima
Stofko, Larry	St. Joseph Health System
Stovall, Heidi	MiVIA
Suennen, Lisa	
Verbeten, Nileen	Nileen Verbeten
Wallis, Kier	Manatt Health Solutions
WILDLAKE, CHRISTINA	
Wilner, Julie	Google Health
Yang, Thomas	

**State of California
HEALTH AND HUMAN SERVICES AGENCY
Patient Engagement Workgroup Charter**

Workgroup Charter

Name:	Patient Engagement	Co-Chairs:	TBD
Meeting Frequency:	Likely Bi-weekly	Consultants:	• Manatt Health Solutions

Reporting Structure: The Workgroup is convened under the authority of the Secretary of Health and Human Services Agency, and it reports, on an interim basis, to the Deputy Secretary, HIT, and the eHealth Advisory Board. The Workgroup will work cooperatively with the Operations Team and other Workgroups or Committees established in support of California's eHealth initiative. It is anticipated that the Workgroup will be incorporated into the Governance Entity structure once the Governance Entity is selected and that structure is put into place.

Linkage to other activities: Other efforts, such as the California Privacy and Security Board (CalPSAB), Medi-Cal meaningful use program, workforce training, regional extension centers and others must be incorporated into the process as appropriate. As necessary, ad hoc committees that include members of CalPSAB and Workgroup members will be created to effectively and quickly deal with issues.

Purpose: This Workgroup will identify innovative approaches to engaging and empowering patients and their families through the use of technology that harnesses the HIE infrastructure, and recommend how to incorporate these approaches into the State's HIE services.

Principles:

1. Patients and their families should have access to and control of their information, and be involved in the process of developing consent and privacy notifications to understand how their data will be used in HIE services.
2. The process for developing an engagement strategy for patients and their families should be collaborative, open, inclusive, fair, and transparent.
3. Meaningful use requirements and HIE services should serve as the foundation for developing a patient and family engagement strategy and recommendations.
4. Patient and family engagement should address how personal health records (PHRs) and other consumer-centric tools factor into overall health management, and the best ways to use PHRs to advance consumer empowerment.
5. Each point of care should be a point of engagement where the patient's provider enables the patient and his or her family to understand and participate in the promise of HIE.
6. The Workgroup should encourage entrepreneurship and a burgeoning competitive commercial marketplace for secure and sound HIE products and services that will encourage patient and family engagement in health care decision making.
7. The greater goal of engaging patients and their families in HIE services is to improve health outcomes. Improving outcomes is achieved by inculcating patients and with a sense of accountability, providing tools to improve medication and treatment regimen adherence, empowering individuals to take an active role in their own health and self-management, and increasing satisfaction with healthcare services.

Goals:

1. Draft a detailed plan for engaging patients and their families with statewide HIE services, and to develop an engagement strategy to be incorporated into the Operational Plan.
2. Define key elements, timeline, and resources required for a patient and family engagement strategy, including specific tools to ensure that patients and families have access to and control of their health information.
3. Create patient and family education materials and patient awareness initiatives, and address educational need to show that patients and families' participation as technology and data-enabled partners in the care process is key to improving the patient's health outcomes.
4. Recommend patient and family engagement programs to assist the HIE Governance Entity and the State to put the expected \$38.8 million in HITECH grant funding to the best and highest use.
5. Develop patient- and family-centric use cases to ensure that implementation maintains a focus on patient

involvement and inclusion.

6. Define metrics and measurement tools to ensure that patient and family engagement objectives are being met.
7. To garner support, consensus and endorsement from California providers, policymakers consumer advocacy networks, eHealth and Health 2.0 innovators in patient self-management tools, and providers, payers and other stakeholders working to foster patient and family engagement with HIE services.

Areas of Responsibility:

- Good faith participation in a collaborative process involving all stakeholders with shared as well as differing interests
- Thoughtful input into and careful review of patient engagement strategies, educational materials, and awareness initiatives
- Discussion and refinement of patient and family engagement strategies and programs in an open, collaborative process.
- Ensuring that all stakeholders are afforded the opportunity to participate in the process
- Prioritizing patient- and family-centered use cases to inform decision-making
- Wide communication of and awareness building for this effort to stakeholders across California

Operational Plan Requirements & Deliverables:

- Patient engagement strategy for inclusion in the operational plan, defining key elements, timeline, and resources required to implement the strategy
- Requirements for incorporation into the technical design to ensure that meaningful use requirements, as well as mechanisms for patient and family access and control are incorporated into HIE services
- Communications plan to facilitate patient and family education and awareness of HIE and tools for patient access and control of their health information, leveraging industry knowledge to understand patients and target messaging.
- Metrics and measurement tools to ensure that objectives of the patient and family engagement strategy are monitored and met
- Patient Engagement Workgroup project schedule (2010 - 2013)
- Patient Engagement Workgroup staffing plans
- Patient Engagement Workgroup cost estimates
- Issue identification and risk mitigation strategies

Suggested Timeline for Completion of Operational Plan Deliverables

- December 7, 2009: Workgroup kickoff meeting to review and confirm Workgroup charter and timeline; Develop work plan to complete identified Operational Plan deliverables
- January 4, 2010: Initial drafts or outlines of deliverables for Operational Plan
- February 1: Workgroup Summit to review initial draft of Operational Plan
- February 5: Second draft of deliverables for Operational Plan
- March 5: Final draft of deliverables for Operational Plan

Other Deliverables

- Garner support, consensus and buy-in from California consumer advocacy networks, eHealth and Health 2.0 innovators in self-management tools for patients and their families, and providers, payers and other Stakeholders working to foster patient engagement with HIE services
- Measure and monitor progress against defined metrics and recommend actions to ensure patient and family engagement strategy objectives are met on a timely basis

**State of California
HEALTH AND HUMAN SERVICES AGENCY
Financing Workgroup Charter - DRAFT**

Workgroup Charter

Name:	Financing Workgroup	Co-Chairs:	TBD
Meeting Frequency:	Likely Bi-weekly	Consultants:	Manatt Health Solutions Alana Ketchel

Reporting Structure: The Workgroup is convened under the authority of the Secretary of Health and Human Services Agency, and it reports, on an interim basis, to the Deputy Secretary, HIT, and the eHealth Advisory Board. The Workgroup will work cooperatively with the Operations Committee and other Workgroups or Committees established in support of California's eHealth initiatives. It is anticipated that the Workgroup will be incorporated into the Governance Entity structure once the Governance Entity is selected and that structure is put into place.

Linkage to other activities: Other efforts, such as the California Privacy and Security Board (CalPSAB), Medi-Cal meaningful use program, workforce training, regional extension centers (RECs), and others must be incorporated into the process as appropriate. As necessary, ad hoc committees that include members of these and other organizations and Workgroup members will be created to effectively and quickly deal with issues.

Purpose: Recognizing that the creation of a robust health information exchange (HIE) infrastructure in California will depend on its ability to secure the financial capital to build infrastructure capabilities and develop ongoing revenue streams to maintain operations, the Financing Workgroup will address the need to develop financing strategies and sustainability models for HIE in California.

Principles:

1. The process for developing and evaluating sustainability models and financing strategies should be a collaborative, open, inclusive, fair and transparent. Such a process will engender trust and collaboration between and among stakeholders.
2. HIE financing strategies should consider how to leverage the Medicare and Medicaid meaningful use incentives that are anticipated to create demand for products and services that enable HIE among eligible providers.
3. The proposed financing strategies and sustainability models should support a means for providers to achieve meaningful use and address disparities in providers' abilities to secure financial capital.
4. The State's financial and technical assets, including access to ARRA administrative matching funds and CMS "meaningful use" incentive payments, should be leveraged to support the development of financing strategies sustainability models for HIE infrastructure.
5. Public and private sector assets, including existing investments in health IT and HIE, should be leveraged to support the creation of a robust HIE infrastructure.
6. The Workgroup should coordinate with efforts currently underway in California, including other workgroups that are part of the current process, CalPSAB, the Medi-Cal meaningful use program, REC programs, California Health Financing Facilities Authority (CHFFA), and other identified efforts.

Goals:

1. To develop financing strategies that will enable the provision of high-value HIE services, including those that support meaningful use and others that generate sustainable demand.
2. To develop cost estimates for achieving statewide HIE (total cost of HIE infrastructure)
3. To develop policy recommendations for financing strategies and sustainability models that may be incorporated into the Operational Plan for submission to the Office of the National Coordinator for Health IT (ONC) on March 31, 2010.
4. To ensure that requirements of the expected HIE participants are incorporated into and supported by the HIE infrastructure; expected HIE participants include: consumers, hospitals, ambulatory care providers, health plans, health information organizations (HIOs), government and others.
5. To garner support, consensus, and buy-in from California stakeholders around financing strategies and sustainability models for HIE in California.

Areas of Responsibility:

- Good faith participation in a collaborative process involving all stakeholders with shared as well as differing interests.
- Thoughtful input into and careful review of proposed financing strategies and sustainability models.
- Discussion and refinement of proposed strategies and models.
- Ensuring that all stakeholders are afforded the opportunity to participate in the process.
- Prioritizing the needs of providers serving underserved and vulnerable populations.
- Wide communication of and awareness building for this effort to stakeholders across California

Operational Plan Requirements & Deliverables

- Financing strategies and sustainability model for inclusion in the Operational Plan
 - Identification of possible revenue sources, including tax subscription models and possible loan funds
 - Proposed approach to build sustainability model to support CA HIE services
- Estimated costs for statewide HIE in California
- Finance Workgroup Project schedule (2010 - 2013)
- Finance Workgroup Staffing plans
- Finance Workgroup Cost estimates
- Issue Identification and risk mitigation strategies
- Metrics and measurement tools to ensure that objectives are met

Suggested Timeline for Completion of Operational Plan Deliverables

- December 7, 2009: Workgroup kickoff meeting to review and confirm Workgroup charter and timeline; Develop work plan to complete identified Operational Plan deliverables
- January 4, 2010: Initial drafts or outlines of deliverables for Operational Plan
- February 1: Workgroup Summit to review initial draft Operational Plan
- February 5: Second draft of deliverables for Operational Plan
- March 5: Final draft of deliverables for Operational Plan

Other Deliverables (required completion by April 2011)

- Revenue source identification, including tax and subscription models and possible loan funds
- Sustainable business model for statewide HIE services including pricing strategy
- Detailed plan to administer sustainable revenue to support CA HIE services, including budget, available funding sources, and recommendations

**State of California
HEALTH AND HUMAN SERVICES AGENCY
Underserved and Vulnerable Populations Workgroup Charter - DRAFT**

Workgroup Charter

Name:	Underserved and Vulnerable Populations	Co-Chairs:	TBD
Meeting Frequency:	Likely Bi-weekly	Consultants:	Manatt Health Solutions Alana Ketchel

Reporting Structure: The Workgroup is convened under the authority of the Secretary of Health and Human Services Agency, and it reports, on an interim basis, to the Deputy Secretary, HIT, and the eHealth Advisory Board. The Workgroup will work cooperatively with the Operations Team and other Workgroups or Committees established in support of California's eHealth initiative. It is anticipated that the Workgroup will be incorporated into the Governance Entity structure once the Governance Entity is selected and that structure is put into place.

Linkage to other activities: Other efforts, such as the California Privacy and Security Board (CalPSAB), Medi-Cal meaningful use program, workforce training, regional extension centers and others must be incorporated into the process as appropriate. As necessary, ad hoc committees that include members of CalPSAB and Workgroup members will be created to effectively and quickly deal with issues.

Purpose: This Workgroup will address the specific needs and disparities among vulnerable and underserved populations including children in foster care programs, aging and disabled population (including dual eligibles and those beneficiaries being served through Medi-Cal Managed Care plans), mental health, behavioral health and the uninsured, and incorporate their needs into the operational plan. The Workgroup will develop and recommend a communication and outreach strategy to ensure the considerations and disparities among vulnerable and underserved populations are known and addressed.

Principles:

1. The process for incorporating the needs of the underserved and vulnerable populations into HIE services should be collaborative, open, inclusive, fair and transparent.
2. Meaningful use requirements and HIE services should serve as a foundation for developing tools that serve these populations.
3. HIE services should support community care and improve care for underserved populations, and provide a means for providers to achieve meaningful use, depending on their needs and pre-existing capabilities.
4. The Committee should coordinate with programs supporting California's health care safety net facilities and providers in underserved communities, including Child Support Services, , County Foster Care, Juvenile Justice and Mental Health Programs, Department of Health Care Services programs, California Medical Assistance Program, long-term care and other programs servicing vulnerable populations
5. HIE services must support the aforementioned programs and recognize that California's health care safety net facilities and providers in underserved communities generally face significant fiscal and resource challenges

Goals:

1. To assist the Technical Workgroup, Operations Team, HIE Governance Entity and CHHS to enable statewide HIE while addressing the specific needs of the underserved and vulnerable populations and working to eliminate disparities in care.
2. To ensure that federally defined and California Medi-Cal requirements for addressing the needs of these populations are met to assist the HIE Governance Entity and the State to put the expected \$38.8 million in HITECH grant funding to the best and highest use.
3. To ensure that requirements of the expected participants in HIE are incorporated into specific tools and functions developed or these populations; expected participants include: consumers, hospitals, ambulatory care providers,

<p>health plans, HIOs, government and others</p> <ol style="list-style-type: none"> 4. To garner support, consensus and buy-in from California advocacy groups representing these populations. 5. To ensure that the HIE needs of the various program providing critical services to these populations are addressed and met through the HIE services to be developed 6. To ensure that communication strategies are developed that allow these populations and the programs that serve them to access HIE services
<p><u>Areas of Responsibility:</u></p> <ul style="list-style-type: none"> ➤ Good faith participation in a collaborative process involving all stakeholders with shared as well as differing interests ➤ Thoughtful input into and careful review of the specific communication and education program needs of these populations. ➤ Discussion and refinement of proposed tools and programs for these populations in an open, collaborative process. ➤ Ensuring that all stakeholders are afforded the opportunity to participate in the process ➤ Prioritizing tools and communications programs for these populations to inform decision-making ➤ Wide communication of and awareness building for this effort to stakeholders, representatives, and advocacy groups for these populations.
<p><u>Operational Plan Requirements & Deliverables</u></p> <ul style="list-style-type: none"> ➤ Recommendations and strategy to address the needs and disparities among underserved and vulnerable populations for inclusion in the Operational Plan ➤ Requirements for incorporation into the technical design to ensure that the meaningful use requirements, as well as the needs and disparities among underserved and vulnerable populations are incorporated into HIE services ➤ Communication and outreach strategy to underserved and vulnerable populations that integrates input from groups with experience and insight into the needs of vulnerable and underserved populations (e.g. CHCF, CalPSAB, DHCS, DSS, Juvenile Justice, Long Term Care and Rehabilitation programs, CMAC, Indian Services, and DDS) ➤ Metrics and measurement tools to ensure that needs and disparities among underserved and vulnerable populations as identified in the Operational Plan are monitored and met ➤ Vulnerable and Underserved Populations project schedule (2010 - 2013) ➤ Vulnerable and Underserved Populations staffing plans ➤ Vulnerable and Underserved Populations cost estimates ➤ Issue identification and risk mitigation strategies <p><u>Suggested Timeline for Completion of Operational Plan Deliverables</u></p> <ul style="list-style-type: none"> • December 7, 2009: Workgroup kickoff meeting to review and confirm Workgroup charter and timeline; Develop work plan to complete identified Operational Plan deliverables • January 4, 2010: Initial drafts or outlines of deliverables for Operational Plan • February 1: Workgroup Summit to review initial draft of Operational Plan • February 5: Second draft of deliverables for Operational Plan • March 5: Final draft of deliverables for Operational Plan
<p><u>Other Deliverables</u></p> <ul style="list-style-type: none"> ➤ Ensure that requirements of the expected participants are incorporated into specific tools and functions developed for special populations ➤ Garner support, consensus and buy in from advocacy groups representing underserved and vulnerable populations ➤ Measure and monitor progress against defined metrics and recommend actions to ensure patient engagement strategy objectives are met on a timely basis

Appendix 4: List of eHealth Advisory Board Members

CO-CHAIRS

Kim Belshé, Secretary, California Health and Human Services Agency

Paul Tang, MD, Vice President and Chief Medical Information Officer, Palo Alto Medical Foundation

MEMBERS

Elaine Alquist, Chair, Senate Committee on Health

Karen Bass, Speaker of the Assembly

Patrick Johnston, President and CEO, California Association of Health Plans

Dale Bonner, Secretary, Business, Transportation and Housing Agency

Rachelle Chong, Commissioner, California Public Utilities Commission

Donald Crane, President and CEO, California Association of Physician Groups

Duane Dauner, President, California Hospital Association

Joe Dunn, Chief Executive Officer, California Medical Association

Carmela Castellano Garcia, President and CEO, California Primary Care Association

Karen Hatfield, President, California Clinical Laboratory Association

Melissa Stafford Jones, President and CEO, California Association of Public Hospitals

Sam Karp, Vice President of Programs, California HealthCare Foundation

David Lansky, PhD, President and CEO, Pacific Business Group on Health

Ken McEldowney, Executive Director, Consumer Action

Lynn Rolston, Chief Executive Officer, California Pharmacists Association

Teri Takai, State Chief Information Officer, Office of the State Chief Information Officer

Ben Wilson, Director of Healthcare IT, Intel Digital Health Group

Appendix 5: List of Operations Team Members

Operations Team	
Name	Organization
Andrews, Tim	High Pine Associates, LLC
Ange, Erika	The Lewin Group
Ashton, Lisa	Mercy Medical Group, CHWMF
Barr, Justin	
Barr, Lynn	CHHS
Barrow, Steve	CA State Rural Health Association
Boynnton, Ann	Manatt Health Solutions
Chan, Albert	Palo Alto Medical Foundation
Christman, Scott	CA Dept. of Public Health
Doebbert, Gwendolyn	CHHS
Frohlich, Jonah	California Health and Human Services Agency
Goltz, Amanda	Manatt Health Solutions
Henry, Steven	UnitedHealth Group
Holm, Bobbie	CHHS- CalOHII
Kam, Alex	Office of health Information Integrity
Ketchel, Alana	CHHS
Kirkwood, Mike	Polka
Kuhmerker, Kathy	The Lewin Group
Landry, Laura	Long Beach Network for Health
Leahy, Kevin	CHHS- CalOHII
Leslie, Timathie	
Oprendek, Stephanie	California Institute for Mental Health
Ortiz, Kim	Medi-Cal
Ozeran, Larry	Clinical Informatics, Inc
Ray, Joseph	Manatt Health Solutions
Sass, Wayne	Nautilus Healthcare Management Group
Schmoeckel, Christine	CHHS- CalOHII
Scott, Linette	CA Dept. of Public Health
Stofko, Larry	St. Joseph Health System
Sujansky, Walter	Sujansky & Associates, LLC
Wallis, Kier	Manatt Health Solutions

Appendix 6: Request for Information for Governance Entity



**Request for Information:
Potential Health Information Exchange Governance Entity**

I.	Purpose of this Request for Information	Error! Bookmark not defined.
II.	A Framework for HIE	Error! Bookmark not defined.
III.	Role of California's HIE Governance Entity	Error! Bookmark not defined.
IV.	RFI Response Format and Content	Error! Bookmark not defined.
V.	Evaluation	Error! Bookmark not defined.
VI.	HIE Governance Entity Proposed Areas of Responsibility	Error! Bookmark not defined.
	Exhibit A.....	Error! Bookmark not defined.



Request for Information: Potential Health Information Exchange Governance Entity

Purpose of this Request for Information

This Request for Information (RFI) is issued by the California Health and Human Services Agency (CHHS) to determine whether one or more organizations might qualify to be the State's Health Information Exchange (HIE) Governance Entity. CHHS will evaluate responses to the RFI and may, at its sole discretion, at the conclusion of the evaluation process select **one** of the respondents to be the State's HIE Governance Entity. The State reserves the right to initiate confidential discussions with one, some or all applicants regarding any response submitted to ask questions and clarify respondent intent and meaning. These discussions may include suggestions from the State to revise one or more aspect of the response.

The State may determine that no respondent will be selected as the HIE Governance Entity.

If the State selects an HIE Governance Entity, it is possible that the HIE Governance Entity will become the State-Designated Entity, as defined in Section 3013 of the Health Information Technology for Economic and Clinical Health Act' (HITECH), and therefore eligible to apply for specific federal funds on the State's behalf. The State may elect not to use a State-Designated Entity and instead apply directly for funds.

The purpose of California's advancement of health information technology and exchange is to improve safe and secure patient and provider access to personal health information and decision-making processes, benefiting the health and wellbeing, safety, efficiency, and quality of care for all Californians.

This purpose is supported by the following goals:

To ensure patients have safe, secure access to their personal health information and the ability to share that information with others involved in their care

To engage in an open, inclusive, collaborative, public-private process that supports widespread EHR adoption and a robust, sustainable Statewide health information exchange

To improve health care outcomes and reduce costs

To maximize California stakeholders' access to critical ARRA stimulus funds

To integrate and synchronize the planning and implementation of HIE, HIT, telehealth and provider incentive program components of the federal stimulus act

To ensure accountability in the expenditure of public funds

To improve public and population health through stronger public health program integration, bio-surveillance and emergency response capabilities

Please refer to www.hie.ca.gov for additional details of the State's initiatives in this area.

The Federal Office of the National Coordinator released the funding opportunity announcement for the *State Health Information Exchange Cooperative Agreement Program* on August 20, 2009. Selection of a HIE Governance Entity is, therefore, on an accelerated timeline and this process reflects that sense of urgency.

A Framework for HIE

The following framework describes the State's priorities for health information exchange. This framework has four components or "corners"; information exchange priorities that support meaningful use, trust, a technical model, and sustainability. Applicants to this RFI should use this framework to develop and submit proposals

HIE priorities - achieving meaningful use: Eligible hospitals, clinics and providers will be required to exchange health information to achieve meaningful electronic health record use and thereby obtain Medi-Cal and Medicare incentives payments. To support these requirements, California's health information exchange capabilities must be expanded rapidly and align with meaningful use. These health information exchange meaningful use priorities include:

Electronic prescribing and refill requests, including prescription fill status / medication fill history

Clinical laboratory ordering and results delivery

Clinical summary exchange for care coordination and patient engagement

Electronic public health reporting (e.g., immunizations, laboratory results, etc.)

Trust: HIE infrastructure must be developed and sustained in an environment that fosters trust. This requires an open, inclusive and transparent process that is respectful of divergent views, but that drives a process towards consensus. Any initiative that does not make this a top priority will not succeed.

A Supportable Technical Architecture: California has assets that should be leveraged to support HIE. These assets include: hospital, clinic and practice based electronic health record systems, functioning and nascent information exchanges, broadband networks, public health registries, lab and reporting systems, and pharmacy and lab networks. These assets can and should support a vendor-agnostic, service-oriented HIE model.

Sustainability: California may receive up to \$40 million in Federal funding for HIE. While this is a significant investment it represents only a fraction of what is ultimately needed to develop and sustain ubiquitous HIE services. Any HIE model must determine how funding will be obtained to further build out the infrastructure, and to sustain exchange that is built once the \$40 million is invested. The sustainability model must encompass all aspects of exchange, including regional and other health information exchanges.

Finally, during the planning process, CHHS received stakeholder feedback indicating that there should be a separation between a governance entity and operating entities that build and maintain the HIE. However, this separation does not rule out that centrally operated services could be sponsored by the HIE Governance Entity, either through contracts or more direct oversight and management. Such services could only be sponsored by the HIE Governance Entity if the services are requested and driven by the critical stakeholders: hospitals, physicians, health plans and payers, consumers and other providers. Respondents to this RFI will need to describe how such a separation would either bolster or undermine efforts to support HIE efforts, specifically with respect to the four corners of the framework referenced here.

Responses to the RFI must address how a governance entity would invest up to \$40 million to support these priorities to develop and sustain HIE infrastructure in California.

Role of California's HIE Governance Entity

California must align its health information exchange implementation and priorities with the current federal definition of meaningful use to ensure that its eligible Medicare and Medi-Cal providers are able to demonstrate meaningful use and are positioned to receive the maximum incentive reimbursement and avoid future reimbursement penalties. With this as an imperative, immediate priorities have been delineated to support Medicare and Medi-Cal provider. CHHS will work with the HIE Governance Entity to coordinate activities across California and its many stakeholders, including Medi-Cal and State and local public health programs. The Governance Entity's primary responsibilities will, at a minimum, include:

Establishing a technical architecture that is vendor-agnostic and leverages California's information technology infrastructure to enable the rapid propagation of information exchange services across the State.

Convene a broad array of hospitals, physicians, other providers and other stakeholders to agree to and support a set of shared services.

Determine the most efficient way to spend limited funding to support the identified priorities of lab data exchange, pharmacy / Rx history, continuity of care, and public health, and other priorities as identified by the institutions engaged in health information exchange.

Perpetuate and support HIE services beyond stimulus funding.

These responsibilities must also support the priorities described in the State HIE Cooperative Agreement Program announced by ONC on August 20. In that announcement, ONC expects States to use their authority, programs, and resources to:

Develop State level directories and enable technical services for HIE within and across States.

Remove barriers and create enablers for HIE, particularly those related to interoperability across laboratories, hospitals, clinician offices, health plans and other health information trading partners.

Convene health care stakeholders to ensure trust and support for a Statewide approach to HIE.

Ensure that an effective model for HIE governance and accountability is in place.

Coordinate an integrated approach with Medicaid and State public health programs to enable information exchange and support monitoring of provider participation in HIE as required for Medicaid meaningful use incentives.

Develop or update privacy and security requirements for HIE within and across State borders.

In addition, States may choose to enter into multi-State arrangements. States submitting multi-State applications will be evaluated at both the multi-State and individual State level; the multi-State plan will be evaluated as a whole, but State plans must be sufficient at the individual State level as well. For multi-State applications, one State or SDE must act as the responsible fiscal agent.

Additional areas of responsibility can be found in Section VI. HIE Governance Entity Proposed Areas of Responsibility. Specific organizational requirements can be found in Exhibit A.

The Secretary of CHHS may also convene an Advisory Committee to advise the work of the HIE Governance Entity. The HIE Governance Entity will work cooperatively with any such Committee and other State of California sponsored committees, Boards, Departments and Agencies in the conduct of all activities.

RFI Response Format and Content

This section articulates the RFI Response format and content. CHHS encourages respondents to be thorough, thoughtful and succinct. Response Sections 2 and 3 are expected to be in a detailed narrative. Narratives must be in 12 point font and limited to 10 pages or less for both Sections. The 10 page limit does not apply to the Cover Letter, Interim Financing, Organizational Requirements Matrix, Biographies and Letters of Support. Please do not include any other attachments.

Submission and Timeline

Proposals must be submitted electronically to hie@chhs.ca.gov no later than **5pm PDT, Thursday September 10, 2009**. Responses will be reviewed against the criteria defined in this RFI by a selection committee comprised of State employees. The selection committee will evaluate and score each proposal separately. Selection committee consensus scores will be made public and are not subject to appeal or protest. CHHS will respond to RFI applicants no later than Tuesday September 29, 2009.

The response must be presented in the following sections and in the following order:

Cover letter

Signed by an individual legally authorized to bind the organization

Governance entity approach and plan

Each response must lay out a plan for meeting the Federal and State requirements. Assuming California or its designee applies for and receives up to \$40 million in federal funding to support HIE adoption, respondents should detail their plans and approach regarding how they intend to work with California and CHHS to:

- Establish a technical architecture and standards.
- Establish privacy and security standards and enforcement.
- Define the set of State-level shared services and repositories for California.
- Rollout services and propagating throughout California.
- Achieve sustainability in order to perpetuate and support the HIE infrastructure beyond the potential \$40M in federal funding.
- Analysis of whether the State should pursue a multi-State approach and why

The respondents' plans should be specific and succinct. Responses must specifically outline the following for each of the items above:

- The role of the governance entity and the staffing model of the organization.
- How dollars will be spent by the governance entity for its own operations as well as for dispersed funds for HIE services.
- Timeframes for all activities.
- How existing investments and existing HIE activity will be leveraged.
- How the approach will achieve trust, participation, buy-in and, ultimately, adoption among stakeholders.

Separation of governance from operations

CHHS received strong stakeholder feedback during the planning process that Stated that there needs to be a separation of governance from operations in the governance entity. However, this separation does not rule out centrally operated services. Respondents are asked to respond to the following:

- How does the separation of governance from operations impact the components of the respondents plan and approach above? Specifically comment on the impacts to stakeholder buy-in and trust as well as costs.
- Given the separation of governance from operations, what is the governance entity's role in providing State-level services?
- What process would be used to determine if and when it might be appropriate for the HIE Governance Entity to initiate the provision of some services?

Interim Financing

Please provide a chart that clarifies the financial needs of the organization, including salaries and benefits, contract costs (and types of contracts anticipated), rent and other facilities costs, travel, other expenses.

Organizational requirements matrix

Exhibit A provides other specific requirements of the Governance Entity, and asks you to describe how your organization currently meets these requirements and, where there are gaps, how you propose to meet the requirements. The overall timeline for achieving electronic health record meaningful use for eligible providers is very short. The State must work expeditiously to do its part to maximize the potential reimbursement for which providers are eligible. As a result, we have determined that the HIE Governance Entity should meet all of the established requirements by March 31, 2010. Please note that it is not necessary that the respondent currently meet all of the requirements in order to submit a response to this RFI. In developing the response, emphasis should be placed on clearly articulating a feasible plan to meet the requirements.

Respondents must complete Exhibit A and include it as the response. Description of how the current organization meets the Requirements, gaps identified between the current organization and the Requirements and the plan to bring the organization into compliance with each Requirement.

Exhibit A below contains four columns.

Requirement: This column contains the specific requirement that must be met by March 2010.

Current Organization: In this column, describe how and to what extent your current organization meets the requirement.

Identified Gaps: In this column, describe the gap between the current organization and the requirement. Describe how the current organization fails to fully meet the requirement.

Strategy to Address the Gap: In this column, describe the proposed strategy to address the identified gaps. This strategy should include estimated resource needs (personnel and financial) and timeline for filling the gap.

Biographies

Brief biographies (1-3 pages) of Board members and senior executives (current and proposed to the extent known).

Letters of Support

Please provide letters of support from various stakeholder organizations within California. Letters of support should be from different stakeholder types (e.g. hospital or hospital system, provider group, RHIO, consumer group, community health center, etc.). Letters of support should come from more than one region within the State. Safety net organizations should be well represented in the letters of support. An applicant that proposes a multi-State plan should provide letters of support from other States.

An applicant that proposes a multi-State plan should provide letters of support from other States.

Evaluation

The CHHS will evaluate each organization's proposal individually and assign a score to each section. In assigning scores, the Selection Committee will take into consideration the severity of the gaps (if any) between the current organization and the requirements and the overall feasibility of the proposal to resolve these gaps. CHHS reserves the right to talk with any or all respondents about their response to this RFI as part of the evaluation process. All such discussions will be confidential.

HIE Governance Entity Proposed Areas of Responsibility

Convene	Coordinate	Manage
<ul style="list-style-type: none"> ■ Provide neutral forum for all stakeholders ■ Educate constituents & inform HIE policy deliberations ■ Advocate for Statewide HIE ■ Serve as an information resource for local HIE and health IT activities ■ Track/assess national HIE and health IT efforts ■ Facilitate consumer input 	<ul style="list-style-type: none"> ■ Develop and lead plan for implementation of Statewide solutions for interoperability. ■ Promote consistency and effectiveness of Statewide HIE policies and practices ■ Support integration of HIE efforts with other healthcare goals, objectives, & initiatives ■ Facilitate alignment of Statewide, interstate, & national HIE strategies, RECs, Medi-Cal, etc. ■ Coordinate with CalPSAB around privacy and security policies 	<ul style="list-style-type: none"> ■ Issue and manage grants ■ Develop legal analyses ■ Oversee accounting and budgeting ■ Possibly contract for Statewide shared services such as master patient index ■ Evaluation and assessment ■ (Multi-State scenario only): manage and support other State HIE programs

Exhibit A

Requirement	Current Organization	Identified Gaps	Strategy to Address Gap
Organizational			
Not-for-profit organization under California law			
Diverse board composition from multiple types of organizations from multiple regions throughout the State			
Board must include: Secretary of CHHS, the Deputy Secretary of HIT, representatives from the Senate and the Assembly and others as deemed necessary by the Secretary of CHHS as voting members of the HIE Governance Entity			
Experienced and qualified executive management team and staff, who act under the direction of the Organization's Board of Directors to address privacy and security, technical approach and health IT adoption			
Adequate workgroups and subcommittees to reasonably accomplish State HIT/HIE goals			
Demonstration that one of its principle goals is to use information technology to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information			
Commitment to protect the public's interests and ensure accountability of HIEs in the State			
Nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair and nondiscriminatory participation by stakeholders			
Does not directly operate a HIE or have any financial stake in a HIE or HIE vendor			

Requirement	Current Organization	Identified Gaps	Strategy to Address Gap
Articles of Incorporation and Bylaws that clearly describe who the members are, how members are selected, and the powers that members will have			
Appropriate insurance			
Trusted, independent voice that can reflect a diverse array of interests and perspectives on key policies and standards			
Ability to convene and facilitate multiple collaborative, workgroups in an open, public and transparent way that are represented by institutions and individuals from all regions of California (and if multi-State, other States and their constituents). Demonstrated expertise in the following workgroup functions would include but not be limited to: Health Outcomes Privacy and Security Technical Approach Sustainability Health IT Adoption			
Experience with outreach and advocacy, specifically the advocacy of HIE			
Support the development and promulgation of Statewide HIE policies			
Health Outcomes			
Support federal requirements and goals described in Section 3013 of the Health Information Technology for Economic and Clinical Health Act' (HITECH)			
Ensure that California's 2010 and 2020 health outcome goals and appropriate regional health outcomes goals and priorities are supported by HIE activities			
Privacy and Security			
Coordinate with CalPSAB to define privacy and security policy and guidance			

Requirement	Current Organization	Identified Gaps	Strategy to Address Gap
Ability to monitor implementation of California's privacy and security policy and guidance and, work with appropriate State agencies to enforce them			
Demonstrated knowledge and experience of existing privacy and security issues			
Technical			
Ability to track, assess and align California HIE and HIT efforts with national HIE and health IT efforts and standards. Support, promulgate, and where necessary develop interoperability standards			
Technical expertise on staff with the ability to manage complex technology policies and practices			
Ability to define, prioritize, select, leverage and manage shared health it services across a wide range of stakeholders			
Management			
Demonstrated ability to acquire and train appropriate resources			
Experience in managing contracts for various types of services including: Technology Legal Administrative Professional			
Have a plan to coordinate and collaborate with other critical California health IT efforts, including, but not limited to: Medi-Cal Public health Regional extension centers Workforce initiatives Broadband and telehealth			
Implement a dispute resolution mechanism to adequately and appropriately reconcile divergent opinions and perspectives			

Requirement	Current Organization	Identified Gaps	Strategy to Address Gap
Multi-State proposals should define commitments to working with other States and describe the advantages that a multi-State approach would confer to California			
Evaluation and Assessment			
Evaluation and assessment experience in complex programmatic and fiscal environments focused on health improvement.			
<p>Develop evaluation and accountability measures and framework for HIE implementation and health IT initiatives including:</p> <p>Assessment of quality improvement benefits created through HIE efforts within the State</p> <p>Tracking and reporting progress of HIE and relevant Health IT initiatives</p> <p>Tracking, assessing, validating and reporting stakeholder activities and progress</p>			
Financial			
Experience in development and administration of grant-making processes consistent with State and Federal Guidelines, including experience managing large Federal grants			
Proven experience with raising funds from multiple sources – both public and private			
Robust administrative and financial processes, including adherence to GAAP and all federal and State laws			
A plan for supporting ongoing operations and oversight without public resources or funding			

Appendix 7: California HIE Financial Model

This Operational Plan is a living document, and will be updated on an ongoing basis. This section will be revised at a future time.

Appendix 8: Tool for Collecting Strategies for Patient Engagement

Tool for Gathering Patient Engagement Content for Operational Plan

Instructions: Please fill in the boxes with any examples or use cases that you believe we should address in the workgroup.

Not every box may need an entry.

MU Goals and Goals/Objectives	Draft: Team Lead, Team Member for Jan 4/11	Final, Team Lead for March 29	Strategy Summary	Electronic prescribing and refill requests including sharing med lists with patient	Clinical laboratory ordering and results delivery	Clinical summary exchange for care coordination and patient engagement	Recommend tools to ensure that patients have access/control of their health information	Improve health outcomes (reminders, decision support)	Inculcate patient with sense of accountability for health	Insurance eligibility checks and portability of patient information to payor	Improve medication and treatment regimen adherence	Empower individuals to take active role in their own health	Using the Teachable Moment to Engage Patients in Care
Consumer / Patient measurements of success "how do we know it worked"?													
Electronic access for patients				How does Electronic prescribing connect with the goal of electronic records being accessible to patients, and between providers									
Patient-specific educational resources													
Clinical summaries for each patient encounter													
Access for all patients to PHR populated real time with health data													
Offer patient-provider secure messaging capability													

MU Goals and Goals/Objectives	Draft: Team Lead, Team Member for Jan 4/11	Final, Team Lead for March 29	Strategy Summary	Electronic prescribing and refill requests including sharing med lists with patient	Clinical laboratory ordering and results delivery	Clinical summary exchange for care coordination and patient engagement	Recommend tools to ensure that patients have access/control of their health information	Improve health outcomes (reminders, decision support)	Inculcate patient with sense of accountability for health	Insurance eligibility checks and portability of patient information to payor	Improve medication and treatment regimen adherence	Empower individuals to take active role in their own health	Using the Teachable Moment to Engage Patients in Care
Provide access to patient-specific educational resources in primary language													
Record patient preferences including ability to opt-out													
Documentation of family medical history													
Upload data from home monitoring devices													
Mobile, entertainment, and games												UC 9-13: The potential of cell phones to supplement the delivery of health- care services will continue to grow and lead to more sophisticated and personalized applications.	
Patients have access to self-management tools													
Electronic reporting care plan, costs, and on experience of care													
Performance metrics for measuring achievement of patient engagement objectives													

MU Goals and Goals/Objectives	Draft: Team Lead, Team Member for Jan 4/11	Final, Team Lead for March 29	Strategy Summary	Electronic prescribing and refill requests including sharing med lists with patient	Clinical laboratory ordering and results delivery	Clinical summary exchange for care coordination and patient engagement	Recommend tools to ensure that patients have access/control of their health information	Improve health outcomes (reminders, decision support)	Inculcate patient with sense of accountability for health	Insurance eligibility checks and portability of patient information to payor	Improve medication and treatment regimen adherence	Empower individuals to take active role in their own health	Using the Teachable Moment to Engage Patients in Care
Recommendations for communications plan to patients and families	Robin												
Issue identification and risk mitigation strategies													
Promote family engagement													
Competitive commercial marketplace													

Appendix 9: Technical Advisory Group Business Requirements Matrix

Meaningful Use Criterion	Relevant HIE Capability	Proposed Cooperative Shared HIE Service	Relative Value	Efficiencies Achieved	Revenue Generating?	Envisioned Purchasers of the Service	Relative Effort	Anticipated Barriers	Aligned Incentives	Must Have vs Nice to Have	Sequence
<The relevant M.U. criterion>	<Description of the general HIE capabilities required to achieve the M.U. criterion>	<Description of the specific Service that could be provided under the HIE Cooperative Agreement program to facilitate the relevant HIE capability>	<Value of the proposed CS-HIE Service to stakeholders, given the current market/landscape --Low, Med, High>	<Specific efficiencies that may be created by the proposed CS-HIE Service, both to specific stakeholders and to the collective health care system>	<Would stakeholders be willing to pay for the CS-HIE Service -- Yes/No? If so, in what way -- subscription fee, transaction fee, community tax, etc. ?>	<Who would be willing to pay for the CS-HIE Service?>	<Effort required to develop and provide the proposed CS-HIE Service -- Low, Med, High>	<What are the barriers to the successful development, use, and sustainability of the proposed CS-HIE Service?>	<How well-aligned would the incentives of various stakeholders be to use the proposed CS-HIE Service? -- Low, Med, High>	<How critical is the proposed CS-HIE Service to enabling other elements of HIE, encouraging adoption of CS-HIE infrastructure, etc.>	<Logical sequence in which the proposed CS-HIE Service should be developed relative to other CS-HIE Services -- primary or secondary?>
EXAMPLE											
Incorporate clinical lab-test results into EHR as structured data	Infrastructure for labs to securely transmit structured lab results to the EHR or EHR module of the appropriate provider(s) in the specified standard format. The transmissions may occur directly between labs and EHRs or via a third party.		High				Medium		High	Unknown	

Appendix 10: Scenarios Illustrating Use of HIE Architecture for Meaningful Use

This section contains examples of the way that HIE Services may be used (or not used) by various types of stakeholders to achieve meaningful use. Its purpose is to illustrate the value of the HIE Services where they are needed, the ways that HIE Services may interact with other HIE services available in California, and the options that stakeholders have with respect to using or not using the HIE services to achieve meaningful use.

Electronic transmission of structured lab results to EHRs

Example HIE Use Case:

CareMore Hospital has a lab outreach program for patients seen at the offices of local community physicians. These physicians are scattered around the community in practices of varying sizes using different EHR systems. The hospital is medium-sized and does not have the resources to implement a separate laboratory interface for each of these practices and EHR systems.

Each of the physician practices is registered in the HIE Entity Registry, and all test orders sent to the lab include an identifier for the entity from which the order originated. Each order also includes an identifier for the ordering provider that is unique to the entity. The CareMore hospital lab uses this information to correctly route electronic lab results to the ordering providers.

For each result that it wishes to deliver electronically, the lab system looks up in the HIE Entity Registry the practice from which the test was ordered. Within that registry entry is a URL for an electronic directory of providers at that entity. Larger practices may host their own provider directories. Smaller practices use the HIE Provider Directory Service for this function. The lab submits a query to the directory URL to retrieve specific addressing instructions where the ordering provider may receive lab results.

These addressing instructions include the URL to which the transmission should be directed and one or more sets of communication protocols and data standards that may be used. At least one set of these protocols/standards must conform to the designated standards of the State HIE Cooperative Agreement Program (in this case, this is the protocol and data standard that the lab will use). Also, the URL indicated in these addressing instructions must reference an entity registered with the Entity Registry Service (either the physician practice itself or a registered intermediary, such as an HIO). Based on this information, the lab system generates an appropriately formatted result message (which includes the name

and other identifying information for the patient) and securely transmits this to the indicated entity via the selected communication protocol.

Within this transmission is included the identity of the ordering provider, a digital certificate for CareMore hospital, an authentication assertion signed by CareMore hospital that verifies the lab system that initiated the transaction, and an authorization assertion signed by CareMore hospital that verifies the role of the lab system with respect to the patient, as well as the reason for the information exchange. Before transmitting these data, the lab system verifies that the receiving system specified in the addressing instructions has a valid active entry in the Entity Registry (by ensuring it has an active certificate) and that the actual recipient of the transmission is, in fact, the same entity (by authenticating it at the outset of the transaction).

The address to which a lab result is sent may be:

1. The EHR at ordering provider's practice, in which case the result is loaded into the patient's record in that EHR and the provider is notified.
2. An intermediate routing service that further directs the result to the appropriate EHR. Such a service may be provided by an HIO, by an EHR vendor, or by another entity. In all cases, the routing service that initially receives the result and forwards it to the provider must be a registered entity.

In certain communities, a subset of the physician practices may be able to receive results directly from the hospital lab (perhaps the larger practices), whereas other practices may require an intermediate service for routing and/or translation. In either case, the Entity Registry Service and the Provider Directory Service allow the lab to (1) ascertain the proper routing information by accessing a single source (i.e., the Entity Registry Service) and (2) implement a single protocol to deliver lab results to any community provider via the default protocol required by the State HIE Cooperative Agreement Program.

Note that, for certain ordering providers and/or physician practices, the CareMore Hospital lab could choose to circumvent use of the HIE Entity Registry and the other mechanisms described above to send results directly to the EHR of that lab (for example, a very large practice with whom the hospital already has a legacy lab interface). This interface could continue to operate unchanged if it serves the needs of the hospital and the practice, while the delivery of results to other practices and providers could use the resources of the State HIE Cooperative Agreement Program.

Patient access to health information

Example HIE Use Case:

Dr. Moore is a rheumatologist in a mid-size multi-specialty group, MultiSpec, that has used the “FirstGen” EHR system for several years. FirstGen provides an effective paperless record system for MultiSpec and can export data in the CCD document format, but it is an older product that does not offer a patient-portal module. The product’s vendor is relatively small and does not have the capacity to develop a patient-portal module in the near future.

One of Dr. Moore’s patients, Mary Byrne, has requested to review her lab results and medication list as they are updated in FirstGen. To achieve this, Dr. Moore has advised Mary to open a personal health record account with GoggleVault, a commercial vendor of PHR services. To fulfill the meaningful use criterion, Dr. Moore will send the health information to Mary’s GoggleVault account.

MultiSpec is an entity registered in the HIE Entity Registry Service. The GoggleVault PHR system is also registered there. To authorize Dr. Moore to send data to her GoggleVault account, Mary accesses the HIE Entity Registry via the GoggleVault application and looks up the entry for MultiSpec. This entry contains the URL for the provider registry of MultiSpec, which may reference a registry hosted by MultiSpec itself or may reference the HIE Provider Directory Service (depending on how MultiSpec has chosen to publish its provider directory). The GoggleVault application submits a query to this URL to display to Mary the providers at MultiSpec, allowing her to select Dr. Moore and other members of his staff who will be authorized to update her GoggleVault account. Earlier, Mary has provide her unique GoggleVault account ID to Dr. Moore.

When Dr. Moore or his staff wish to send information to Mary’s GoggleVault account, they log into the FirstGen EHR and use it to look up the entry for GoggleVault in the HIE Entity Registry Service (the EHR is capable of interfacing to this service and others provided under the State HIE Cooperative Agreement program). Within this registry entry is a URL that references a directory of services provided by GoggleVault. The FirstGen EHR accesses this directory and retrieves addressing instructions for the “update PHR record” transaction. These instructions are not specific to Mary Byrne, but allow EHRs and other applications to update the PHR records of any specified account holder, provided the update is authorized.

These addressing instructions includes a URL to which such transactions should be sent, as well as one or more sets of communication protocols and data standards that may be used for the transaction. At least one set of these protocols/standards must conform to the designated standards of the Cooperative HIE Agreement Program. The URL address of the GoggleVault PHR system must be registered in the Entity

Registry Service. Using this information, the FirstGen EHR generates an appropriately formatted document and securely transmits it to the indicated entity (GoggleVault) via the selected communication protocol.

Within this transmission is included the GoggleVault account ID for Mary Byrne, a digital certificate for the MultiSpec entity, an authentication assertion signed by the MultiSpec entity that verifies the identity and authentication of the FirstGen user who initiated the transaction, and an authorization assertion signed by the MultiSpec entity that verifies the role of this user with respect to Mary Byrne, as well as the reason for the information exchange. Before transmitting these data, the lab system verifies that the receiving system specified in the addressing instructions has a valid active entry in the Entity Registry (by ensuring it has an active certificate) and that the actual recipient of the transmission is, in fact, the same entity (by authenticating it at the outset of the transaction).

Upon receipt of this transmission, the he GoggleVault PHR authenticates the sender as the MultiSpec Group and verifies that MultiSpec has a active entry in the Entity Registry. The entity then uses the authentication assertion, authorization assertion, and Mary Byrne's GoggleVault ID to authorize the loading of the CCD document into Mary Byrne's record.

Provide summary of care records for transitions of care

Example HIE Use Case:

Sea View hospital in San Diego is discharging John Smith after an emergency appendectomy. John Smith's regular physician is Dr. Clarence Hill at the Montrose Internist Group in La Jolla. John Smith has given the staff at Sea View Dr. Hill's name and mailing address, so that Sea View can send Dr. Hill a copy of John's discharge summary. Per the meaningful use criteria, Sea View hospital would like to send the summary electronically. Sea View hospital does not know whether Montrose Internist Group is entirely independent, is part of an IPA, participates in a regional HIO, or uses other commercial services for HIE.

The hospital clerk at Sea View hospital uses the hospital's EHR (which is integrated with the Core HIE Services) to look up the Montrose Internist Group by name in the HIE Entity Registry Service. There are seven Montrose Internist Groups in California, but only one in La Jolla at the address given by John Smith. The hospital clerk selects the entity corresponding to the correct Montrose Internist Group and retrieves the entity's indicated URL for a local registry of providers there. The clerk issues a query to the

directory service at this URL to look up Dr. Clarence Hill and then retrieve his specific addressing instructions for receiving a hospital discharge summary.

These addressing instructions include the URL to which the transmission should be directed on behalf of Dr. Hill and one or more sets of communication protocols and data standards that may be used. At least one set of these protocols/standards must conform to the designated standards of the Cooperative HIE Agreement Program. Also, the URL address indicated in these instructions must reference an entity registered with the Entity Registry Service (either Montrose Internist Group or another entity serving as an intermediary for Montrose). Using this information, the Sea View EHR generates an appropriately formatted discharge summary (which includes the name and other demographic information of John Smith, for purposes of identification) and securely transmits this to the indicated entity via the selected communication protocol.

Within this transmission is included the identity of the receiving principal (Dr. Hill), a digital certificate for Sea View hospital, an authentication assertion signed by Sea View hospital that verifies the identity and authentication of the clerk who initiated the transaction, and an authorization assertion signed by Sea View hospital that verifies the role of the clerk with respect to John Smith, as well as the reason for the information exchange. Before transmitting these data, the lab system verifies that the receiving system specified in the addressing instructions has a valid active entry in the Entity Registry (by ensuring it has an active certificate) and that the actual recipient of the transmission is, in fact, the same entity (by authenticating it at the outset of the transaction).

Upon receipt of this transmission, the receiving entity (which may be Montrose Internist Group or an intermediary, such as an HIO) authenticates the sender as Sea View Hospital and verifies that Sea View has a active entry in the Entity Registry. The entity then delivers the discharge summary to Dr. Hill in whatever way is appropriate. If the entity is the EHR at Montrose Internist Group, it may add the discharge summary to the record of John Smith, and notify Dr. Hill of its arrival. If the entity is an intermediary, such as an HIO, it may forward the entire transmission to the information system at Montrose Internist Group for processing. The authorization decision may be made by either the intermediary system or the EHR at Montrose Internist Group, and will be based on the information within the transmission itself about the sending entity, the sending user, the role of the user with respect to the patient, and the reason for the transaction. The relevant assertions are forwarded with the transaction to whichever entity is required to authorize the transaction.

Variation:

If Montrose Internist Group is small and does not have the means to publish its own provider directory via the required standard mechanism, it may have another entity host its provider directory, such as a local HIO or the HIE Provider Directory Service.

If Sea View Hospital and Montrose Internist Group are part of the same HIO, the services and standards defined under the State HIE Cooperative Agreement Program may not be needed at all for transmitting the discharge summary. The HIO may maintain the registries and directories of all the relevant health care entities within the HIO, manage the authentication and authorization processes, and define the communication protocols and data standards. However, when Sea View Hospital wishes to send a discharge summary to an entity outside the HIO (e.g., in another part of the State), the hospital would need a mechanism to look up that entity in the Entity Registry and perform the other steps required, as described above. In this case, either the HIO could provide a “gateway” to translate between the mechanisms used for internal HIE and the “standard” mechanisms specified under the State HIE Cooperative Agreement Program, or the individual entities in the HIO could themselves support the standard mechanisms when communicating with entities outside the HIO. The same choice would apply to entities within integrated delivery networks or other large organizations.

Exchange of key clinical information among providers and patient-authorized entities

Example HIE Use Case:

Dr. Stenson is a cardiologist at a two-physician practice outside of Sacramento. She has recently referred one of her patients, Frank Taylor, to the UC Davis Medical Center in Sacramento for a mitral valve replacement, and would like to forward key information about Mr. Taylor’s medical history, current medications, allergies, and recent lab results to the hospital. Dr. Stenson’s practice uses an EHR from a major vendor, but it is different than the EHR used by UC Davis. Her EHR is capable of generating a CCD summary document and interacting with the HIE Services available in California.

The exchange of the patient summary between Dr. Stenson and the UC Davis Medical Center is very similar to that of the discharge summary between the Sea View hospital and Dr. Hill, with the exception that UC Davis requires two-factor authentication for users who request information from or supply information to its clinical information systems. Dr. Stenson’s EHR supports password authentication only. Being aware of this limitation, Dr. Stenson has registered herself with the HIE Provider Identity Service, which has rigorously verified her identity and issued her a SecurID card for purposes of two-factor authentication.

Dr. Stenson's EHR can interface to the HIE Provider Identity Service. This enables her to authenticate via the service using her SecurID card and have the authentication token that is generated by the service returned to her EHR. Her EHR then generates an appropriately formatted clinical summary (which includes the name and other demographic information of Frank Taylor, for purposes of identification) and securely transmits this to UC Davis via the supported communication protocol.

Within this transmission is included a digital certificate for Dr. Stenson's practice (i.e., the registered entity), the authentication assertion signed by the HIE Provider Identity Service, and an authorization assertion signed by Dr. Stenson's practice that verifies the role of Dr. Stenson with respect to Frank Taylor, as well as the reason for the information exchange. Because UC Davis trusts the user-provisioning and two-factor authentication performed by the HIE Provider Identity Service, the medical center will authorize the transaction. Note that, with the exception of the authentication assertion, all aspects of this information exchange are comparable to that of the discharge summary exchange described above.

Variation:

Certain entities may not accept even two-factor authentication when performed by counterparties because they lack confidence in the counterparty's procedures for provisioning users and performing authentication, for example, when information is requested or provided by a small practice that is entirely unknown to the entity holding the PHI. In these cases, there may also be a need for users at such practices to authenticate via the HIE Provider Identity Service. This may particularly be the case for entities that are not a party to multi-lateral data-use agreements that otherwise establish trust among counterparties in each others authentication mechanisms.

Submit electronic immunization data

Example HIE Use Case:

St. Jude's, a public hospital clinic, has administered three vaccines to a young child and wishes to submit a record of these vaccinations to a regional immunization registry. The transaction may be initiated by an individual user at the hospital, or it may be initiated automatically by an EHR, a billing system, or some other information system at the hospital. In either case, the vaccination information has already been captured by the hospital's information system, and the hospital wishes to transmit these data electronically to the immunization registry, without a user needing to manually log into the registry and re-enter the data.

The immunization registry has an entry in the Entity Registry Service, which the EHR system at St. Jude's retrieves to begin the transaction. Again, a URL is provided in this registry entry, which allows the hospital to retrieve a directory of services provided by the immunization registry and addressing information for these services. The addressing information includes the appropriate URLs for the services, as well as the supported communication protocols and data standards. The directory is hosted and maintained by the immunization registry. One of the available services is "Add an unsolicited immunization record", which specifies the use of a specific SOAP protocol and the HL7 v2.5.1 message standard with the Common Vaccine Codeset (CVX). Using this information, the hospital EHR generates an appropriately formatted immunization record, which includes the name and other demographic information of the vaccinated child, and securely transmits this to the immunization registry via the indicated communication protocol.

Within this transmission is included the a digital certificate for the St. Jude's entity, an authentication assertion signed by the St. Jude's entity that verifies the identity and authentication of the EHR user who initiated the transaction (or the application that initiated it if it was automated), and an authorization assertion signed by the St. Jude's entity that verifies the role of this user or application with respect to patient, as well as the reason for the information exchange.

Upon receipt of this transmission, the immunization registry authenticates the sender as St. Jude's hospital and verifies that St. Jude's has a valid active entry in the Entity Registry Service. The registry then authorizes the addition of the immunization record based on the attributes of the sending entity, per its digital certificate, the relationship of the authenticated user or system with respect to the patient, and the Stated purpose of the transmission. The registry then matches the patient's demographic information to its own database and adds the immunization data to the appropriate patient record. Because the Entity Registry Service maintains an active listing of all valid entities and their attributes and because the data transmission entailed mutual authentication of the sending and receiving entities, the immunization registry does not need to maintain its own user registry and perform its own authentication process.

Submit reportable lab results electronically

Example HIE Use Case:

BioLife is a small regional laboratory in Redding, CA that performs outpatient testing for physician offices in the community. BioLife recently tested a patient specimen that was positive for hepatitis A, a reportable disease in California. The Lab Information System at BioLife is configured to flag all positive

test results for reportable conditions and send copies of these results CalREDIE, the State's reporting system.

BioLife begins this transaction by retrieving the entry for CalREDIE in the Entity Registry Service. A URL is provided in this registry entry, which allows the L.I.S. to retrieve a directory of services provided by CalREDIE and addressing information for these services. The addressing information includes the appropriate URLs for the services, as well as the supported communication protocols and data standards. The directory is hosted and maintained by CalREDIE. One of the available services is "Submit a Reportable Lab Result", which specifies the use of a specific SOAP protocol, the HL7 v2.5.1 message standard, and LOINC codes. Using this information, the LIS generates an appropriately formatted lab-result message and securely transmits this message to CalREDIE via the indicated communication protocol.

Within this transmission is included the digital certificate for the BioLife entity, an authentication assertion signed by the BioLife entity that verifies the identity and authentication of the L.I.S. process that generated the submission, and an authorization assertion signed by the BioLife entity that verifies the role of this application with respect to patient, as well as the reason for the information exchange.

Upon receipt of this transmission, CalREDIE authenticates the sender as BioLife and verifies that BioLife has a valid active entry in the Entity Registry Service. CalREDIE then authorizes the processing of the lab result based on the attributes of the sending entity (per its digital certificate), the relationship of the authenticated system with respect to the patient, and the Stated purpose of the transmission. CalREDIE then forwards the test result to the appropriate public health database for recording and analysis. Because the Entity Registry Service maintains an active listing of all valid entities and their attributes and because the data transmission entailed mutual authentication of the sending and receiving entities, CalREDIE does not need to maintain its own registry of authorized laboratories and perform its own authentication process.

Exchange of information with non-clinical entities for care coordination

Thomas Cooper is an eight year old child who has recently been placed in a new foster home that is located in a different county from his prior placement. Thomas has been previously diagnosed with asthma and is currently experiencing coughing, shortness of breath, and a tightness in his chest consistent with an asthma attack. His foster parents schedule an appointment for him with the family physician they use for all their family's health care, Dr. Greene. In scheduling the appointment, they inform Dr. Greene's staff that Thomas is in foster care.

Dr. Greene practices at a community clinic that is registered in the HIE Entity Registry Service. California's Statewide Automated Child Welfare Information System (SACWIS) is also registered there. SACWIS provides child welfare case workers with information and tools to manage the needs of children in their caseloads, including tools to maintain the federally-mandated Health and Education Passport (HEP), a key component of the case file of a child living in foster care. The HEP is a document that is intended to store key data about a child in order to supply caseworkers, foster caretakers, and individuals involved in the health and education of the child with essential information about the health and educational status of the child. SACWIS also manages case workers' access to and provision of information via HIE, including authenticating users and managing access controls.

In preparation for Thomas's visit, Dr. Greene's staff uses the clinic's EHR to interface to the HIE Entity Registry Service and access the entry for SACWIS, which allows Dr. Greene's EHR to retrieve a directory of services provided by SACWIS, addressing information for these services, and the supported communication protocols and data standards. The clinic's EHR accesses this directory and retrieves addressing instructions for the "access HEP" transaction. These instructions are not specific to Thomas or his case worker, Dee Andrews, but allow EHRs and other applications to access HEP data for any specific child, provided the access is authorized.

Based on this information, the clinic's EHR securely transmits the "access HEP" transaction to SACWIS. The transmission includes the name and other identifying information for Thomas (for purposes of identification), the identity of the case worker (Dee Andrews), the identity of the treating physician (Dr. Greene), a digital certificate for the clinic, an authentication assertion signed by the clinic that verifies the identity and authentication of the staff member who initiated the transaction, and an authorization assertion signed by the clinic that verifies the role of the staff with respect to Thomas, as well as the reason for the information exchange. Before transmitting the HEP data to the clinic's EHR, SACWIS verifies that the clinic has a valid entry in the HIE Entity Registry (by ensuring that it has an active certificate) and that the actual recipient of the transmission is, in fact, the same entity (by authenticating it at the outset of the transaction). Once verification has occurred, SACWIS transmits the results of the "access HEP" transaction to the clinic's EHR, which delivers it to Dr. Greene.

Once Dr. Greene has completed his visit with Thomas, his staff uses the clinic's EHR to interface to the HIE Entity Registry Service and access the entry for SACWIS, which includes a URL for an electronic directory of case workers. The EHR submits a query to the directory URL to retrieve specific addressing instructions where Dee Andrews may receive summary of care information. The addressing instructions include the URL to which the transmission should be directed and one or more sets of communication

protocols and data standards that may be used. Based on this information, Dr. Greene's EHR generates an appropriately formatted summary of care record and securely transmits it to SACWIS via the selected communication protocol. SACWIS then manages the delivery of the information to Dee Andrews and updates the HEP.

Variation:

If the clinic's EHR does not support the "access HEP" transaction, it may utilize the services of an intermediary, such as an HIO, to perform the required steps to request and receive the results of the transaction on behalf of Dr. Greene and translate them into a standard that is supported by the clinic's EHR.

Run clinical analytics to identify gaps in care with real time delivery of alert messages using advanced clinical decision technology to support care coordination

Francesca Norman is an advanced Type 2 diabetic who has recently seen an endocrinologist, Dr. Evans, at the Multi-Spec Group for hirsutism (abnormal growth of hair). Dr. Evans wants to prescribe a potassium sparing diuretic, spironolactone, to treat the patient. After registering the patient in the group's FirstGen EMR, the EMR calls out to the HIE to reconcile the new record with any prior medication history. When no contraindication is returned, Dr. Evans proceeds to electronically prescribe the diuretic.

Two weeks later Mrs. Norman is with her primary care physician, Dr. Jones, to go over recent kidney tests results that he ordered last month. The results are delivered via the HIE where they are also run through HIEs clinical decision support engine to analyze the lab values against all accessible data that the exchange can access for Mrs. Norman. The kidney results show elevated levels of proteinuria and microalbumin. The decision support engine also finds the recent diagnosis of the patient's hirsutism and a filled prescription for the potassium-sparing diuretic. Because the diuretic elevates the patient's potassium, she is contraindicated for the use of ACE inhibitor which is often prescribed, because of its renal protective indications, for Type 2 patients showing early stage symptoms of Chronic Kidney Disease. When the HIE delivers the kidney lab values to Dr. Jones Uberscripts EMR, an alert accompanies the results advising Dr. Jones of the patient's use of the diuretic and an advisory message includes a reminder on the contraindication of ACE inhibitors in patients with elevated potassium because this can further increase potassium levels which would increase the risk of cardiac-mortality. The CDS alert includes an advisory message that suggests testing the patient's potassium levels and discontinuing the use of the diuretic for two weeks before starting the ACE inhibitor. Dr. Jones clicks on the feedback icon on the alert and types in a note that he has ordered tests to check the patient's potassium levels. He then

posts a reminder note that is routed through the HIE to the patients PHR reminding her to stop taking her diuretic until further notice. When the potassium test order for Mrs. Norman is sent to the lab via the HIE, the order is also routed to the decision support engine which updates its record that the test has been ordered.

Two weeks later, Mrs. Norman returns to Dr. Jones office. The HIE has routed the potassium test results to Dr. Jones' Uberscripts EMR. Prior to their delivery, the potassium lab values have again been run through HIE's decision support engine. As the values are within a normal range for the patient, the decision support engine sends an alert to accompany the lab results advising the physician that the use of ACE inhibitor is no longer contraindicated.

Secure Messaging Use Case

Secure messaging will be an additional service provided through the HIE, not a core service. However, to illustrate some of the thinking behind the principles, strategies, and tactics of patient engagement, a subcommittee of the Patient Engagement workgroup examined the issues related to patient/provider communications that involve secure messaging, exploring how secure messaging would impact the operational nature of patient engagement.

Types of Secure Messaging:

- Between consumer / provider whether initiated by either.
- Between consumer and personal health record.
- Between consumer and administrative elements of health care. This would capture elements like scheduling appointments, requesting referrals, possibly claims tracking. Some may consider this part of the EHR interface. It can include message based prompts and reminders, initiated by clinicians and their staff to remind patients and their advocates, of recommended events and activities that are important to maintaining and improving health.
- Between consumer and education/outreach activities and materials.

Methods of access will dictate the availability and engagement of the consumer in using this service. Examples of such access methods, with specific user types, follows.

Access Method	Consumer/Patient	Provider
Mobile		

Access Method	Consumer/Patient	Provider
▪ Cell Phone	X	X
▪ Smartphone	X	X
▪ Netbook	X	X
▪ Laptop	X	X
Fixed		
▪ Desktop (private)	X	X
▪ Desktop (public, e.g., library)	X	--
▪ Kiosk	X	--
Application		
▪ Secure Applications	X	X
▪ Email		
▪ Social media (e.g., Facebook, Twitter)		

Secure messaging using the access methods listed above may take place through the following channels, provided that each channel can be secured to comply with CalPSAB requirements for protecting the privacy of the users.

- Email (SMTP, POP, IMAP)
- SMS – Neither Secure nor Auditable [Greg Seiler 2/2/2010]
- MMS (multimedia, possibly other formats that are not ‘real-time’)
- Web Services (https and SSL)
- VPN
- Fax
- Voice over IP (VoIP)

In order to create controls and protocols around the use of secure messaging to exchange information via the HIE, the following considerations were developed:

- Administrative Policies
 - Establish policy to obtain opt-in notification and acknowledgement by consumer as to risks.
 - Establish policy as how to provide initial identification of consumer. For example, some organizations may require in person registration for the use of secure messaging.

- Need for policy on content and embedded materials to detail allowable information to be contained in message. The Patient Engagement workgroup and the GE will have to consider whether the information should be structured or whether to allow free text. Similarly, a policy around whether attachments are allowable and whether content or size is restricted will be needed.
- Need for policies to assign accountability, expectations for compliance, and redress of violations of policy.
- Need for policy on archiving secure messages and allowing access to those archives.
- Access Policies
 - Need for protected access for kiosks and other points of public access.
 - Monitoring of data leakage prevention, protection.
 - Encryption (communications channel, endpoints)
 - Need for Breach Notification Policies
 - Notification that information was available for review by the consumer could be done with an “out-of-bounds” notification process such as text message to cellphone.
 - Need for consensus agreements by EHR vendors and other service providers participating in HIE services to assure availability of secure messaging.

The workgroup considered the risks and issues surrounding use of secure messaging as a HIE service. Primarily, it seems likely that all messages will extend beyond the HIE, and may cross over to an external network run by the ISP, the VOIP provider, or other telecommunications provider. Many communications protocols of convenience are not suitable for the transmission of PHI under HIPAA without a patient waiving their rights to privacy under HIPAA. In response, the workgroup developed the principle that messages containing PHI should not be delivered to consumers over non-private, non-secure, non-auditable networks and protocols except where the patient knowingly and intentionally authorizes the sender of PHI to expose their PHI publicly.

Other risks include the possibility of a consumer intentionally divulging his or her access credentials identity to third party who then abuses the knowledge by providing false information to the provider. In

another possible scenario, a connected device registered to a patient is used by an unintended user. For example, a Network Connected Weight Scale registered to a post-MI CHF patient is used by visiting family member who is not the patient, transmitting false information. Finally, the perception of these risks may deter users from using the secure messaging service if it were offered. The Patient Engagement workgroup is tasked with developing mitigation strategies and policies to address these risks as part of a proposal to the GE.

Summary

As the meaningful use criteria, the needs of the California healthcare system, the technical specifications of the NHIN, and the availability and capabilities of the State HIE evolve, the TAC and TWG will modify the set of core and non-core services. As a primary example, as CalPSAB completes the review of privacy and security regulations and provides guidance to the GE, the TAC and TWG are responsible for harmonizing the HIE technical infrastructure to comply with that guidance.

Appendix 11: Financial Models Considered by the Finance Workgroup

Centralized Model

In this approach, the vast majority of the ONC grant funds are used by the State for HIE. The State would identify the services which would best promote HIE in California. It would rank those services and fund as many as the budget would permit. Much of the funding goes to the creation of central HIE infrastructure that is connected to the NHIN. It is expected under this approach that much of the State's HIE traffic is carried by this network through direct connection of participating enterprises and organizations. Local/regional HIOs can continue to operate, and interconnect with the State HIE if they choose (no HIO is obligated to connect). A minimal amount of funding is provided to local/regional HIOs, perhaps only to support connectivity to the State infrastructure. Standards are very important in this strategy as they are required to ensure that information flows as easily as possible.

There are several distinct advantages to this strategy, including:

- Facilitates standardized programs.
- Leverages limited funds well by making shared investments at the center that will benefit all who participate.
- May best support use of technical interoperability standards by making connection to the central infrastructure paramount and uniform.
- May provide the best coordination with large, State-wide providers and insurers who can provide access to larger quantities of relevant patient information (e.g., Kaiser, VA, DoD, Medi-Cal).

Coordination with RECs may be more efficient (CalREC will service most of the State).

There are some distinct limitations as well, including:

- Concentration of power related to HIE is at the center and less in local communities or regions.
- A more uniform HIE deployment at the center may stifle innovation through forced standardization, but could also ensure efficiencies of scale not attainable through local innovation.

- Existing and emerging local/regional HIE projects may feel left out or even threatened by these activities as they are competing for both funds and the attention of stakeholders in their communities. While there is nothing wrong with competing, it should be noted that some local HIOs will compete well while others will not survive.
- Stakeholders may lack the confidence in the State's ability to deploy the HIE effectively.
- Greater proportion of funding may be needed for the GE overhead and administration than other options limiting the impact of the funding.
- State procurement is a lengthy process which will likely delay implementation, possibly for years. The GE, however, will eliminate the need to utilize the State's procurement process.
- The absence of an aggressive requirement for HIE in the CMS measures for 2011 and 2013 is the best argument against a State Heavy approach, because heavy investment may squander scarce resources prior to the establishment of definitive standards.

Mixed Model

In this approach, much of the ONC grant funds will be used by the State for HIE coordination and shared services, but some of the funds would be granted to regional HIOs with novel approaches to explore, potentially with the assistance of HIE start-up companies covering the direct costs. Grants would be awarded to viable HIOs to expand both their scope (the services that they provide) and their scale (the number of providers and hospitals served) to ensure as many eligible hospitals and providers have access to the HIE services needed to attain MU. Funds distributed to regional HIOs are offered through an open, competitive process. State-distributed funds to local/regional HIOs may be tied to connectivity to GE and federal (NHIN) infrastructure and will require use of federal and Statewide interoperability and privacy standards. Grants to HIOs would be made based primarily on the applicability of the approach across the State and on the novelty and potential for leveraging existing resources or reducing costs.

Under this approach, the State creates central HIE infrastructure of its own that will allow for both direct connection by providers and interconnection of regional/local HIOs. The State will leverage existing State and local public and private networks (such as the SAWS network) and review existing public and private HIEs, HIOs and other networks available to support the State and NHIN, including existing Claims Processing companies and Medical Associations that either have or are establishing HIEs. The State will then identify (geographic) gaps in coverage and prioritize based upon items such as population counts, areas known to be of high need, etc. for future coverage. State infrastructure is not merely using the

NHIN backbone alone, but is connected to it. Local/Regional HIOs are not obligated to connect to Statewide infrastructure.

There are several distinct advantages to this strategy, including:

- May be the best of both worlds: balancing between central Statewide services to which any enterprise (large or small) can connect and local/regional initiatives instantiated by HIOs.
- Allows for a critical examination of when it makes sense to provide central services and when to allow local HIOs to be more independent.
- Provides good leverage of limited funds through careful coordination and investment in local/regional activities where it makes sense, and central services where it is most beneficial or necessary due to gaps in HIO coverage.
- Good likelihood of maintaining/enforcing interoperability technical standards.

There are some distinct limitations as well, including:

- May be the worst of both worlds: there may be inadequate funding for either Statewide services or local HIOs because of competition between the two approaches for limited dollars.
- State procurement is a lengthy process which will delay implementation, possibly for years.
- Previous State procurement of large scale health data technology has seen spectacular failures (e.g., WebCMR).
- Local HIOs may feel unable to move forward at their own pace as they wait for Statewide direction and decisions.
- The State may be left behind as local HIOs, not waiting for the State, start their own process of innovation and cooperation.
- The State may adopt unique standards that are incompatible with federal data standards
- Relies on an unproven assumption that health data networking requires substantial State intervention

- It is unlikely that State coordination will escape political pressure.

Decentralized Model

In this approach, much of the ONC grant funds would be granted to regional HIOs under clear guidelines to solve HIE problems whose solutions could reduce costs, resources or time constraints and only the minimum necessary funds will be used by the State for HIE coordination and limited shared services. Grants will be awarded to HIOs to further (or initiate) their deployments. Funds distributed to regional HIOs are offered through an open, competitive process. There is little central State HIE infrastructure in this scenario, providers connect to local/regional HIOs who themselves connect directly to the NHIN as needed. The State would develop the minimum necessary level of shared services, and would coordinate governance of local/regional HIOs to ensure adherence to Statewide policy and standards. Grants to HIOs would be made based primarily on the applicability of the approach across the State and on the novelty and potential for leveraging existing resources or reducing costs.

There are several distinct advantages to this strategy, including:

- Leverage of existing local/regional HIEs to their fullest, allowing current forward momentum to proceed unimpeded and even more encouraged.
- Recognition and reliance on the power of the local nature of healthcare in the State.
- Maximizes the proportion of funds used directly for HIE deployment by distributing more than is held centrally.
- Successful implementation with the lightest possible State participation is more resilient when the State has budget difficulties
- Incentivizes creative solutions
- Places more control and accountability close to the provider through reliance on regional/local HIOs in communities.
- Prevents heavy-handed interference by the State in private sector innovation
- Should support closer coordination between HIE and REC activities directly with providers.

- Implementation may be quicker as local HIOs can make purchase decisions more quickly than a Statewide organization.
- Allows for faster adoption of emerging standards
- Avoids the disincentive of legacy reluctance to adopt new standards, which is inherent in greater State involvement

There are some distinct limitations as well, including:

- May be more difficult to leverage relationships with large, State-wide providers and insurers who can provide access to larger quantities of relevant patient information and often want to do so through centralized facilities and interfaces (e.g., Kaiser, VA, DoD, Medi-Cal).
- Economies of scale harder to leverage as more of the funding is supporting local, potentially duplicative activities.
- Limited expertise harder to leverage as many activities are distributed around the State.
- Some smaller providers, or providers in an area not serviced by a regional/local HIO, may not have an effective way to participate in HIE activities.
- If not managed carefully, interoperability technical standards may be harder to enforce.